(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 September 2002 (12.09.2002)

PCT

(10) International Publication Number
WO 02/070980 A1

(51) International Patent Classification[7]: F41G 3/26

(21) International Application Number: PCT/US02/06604

(22) International Filing Date: 5 March 2002 (05.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/273,733 6 March 2001 (06.03.2001) US
60/273,734 6 March 2001 (06.03.2001) US

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 02/070980 A1

(54) Title: SIMULATION SYSTEM FOR IMAGE-GUIDED MEDICAL PROCEDURES

(57) Abstract: A system and method for computer simulation of image-guided diagnostic and therapeutic procedures such as vascular catheterization, angioplasty, stent, coil and graft placement, embolotherapy and drug infusion therapy. In a preferred aspect, the system is configured to resemble a cardiovascular catheterization laboratory where interventional radiology procedures are performed. A first user (1) may interactively manipulate therapeutic catheters, guidewires and other medical devices (5) in real-time while viewing patient-specific medical image data (2) in a manner similar to that encountered in a clinical procedure.

SIMULATION SYSTEM FOR IMAGE-GUIDED MEDICAL PROCEDURES

Related Applications

This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Application 60/273,733, and to U.S. Provisional Application Serial No. 60/273,734, both filed March 6, 2001, the entireties of which are incorporated by reference herein.

Field of the Invention

The invention relates to a system and method for simulating image-guided medical procedures, particularly those relying on interventional and/or diagnostic devices such as catheters.

Background of the Invention

Interventional radiology provides an alternative to open field surgery. Interventional radiology began as a discipline for diagnosing and treating vascular disease (e.g., such as narrowing of the arteries). The interventional radiologist typically uses a catheter inserted into a blood vessel through a puncture in the skin to gain internal access to the vascular system. Using medical imaging guidance, the catheter is navigated to a target site (e.g., such as the site of a diseased tissue) where it can be used as a conduit through which to pass therapeutic devices. Minimally invasive procedures relying on interventional radiology, including lapraroscopic surgery, cardiovascular interventional radiology, and neurointerventional radiology, have tremendous potential to reduce patient discomfort, complications, hospital stays, post-procedural recovery time and total medical costs.

However, despite the advantages described above, minimally invasive procedures also pose risks. Failure to properly navigate, orient or position catheters and/or other devices within a patient, or failure to properly recognize an anatomic area or pathology to be treated may result in serious injury to a vein, artery, organ, or other internal tissue structure.

Interventional radiologists must perform the delicate eye-hand coordinated movements needed to navigate catheters and therapeutic devices while viewing scanned images of the patient's body cavities or lumens on a flat TV screen. The images are obtained from X-rays, CAT scans, MRI scans, and the like. Depth perception is lacking and it is difficult to learn to control the

instruments through the spatially arbitrary linkage. A mistake in this environment can be dangerous. Without performing the procedure often, there is no way for practitioners to maintain the high degree of skill needed to perform these procedures. It is also impractical to implement new methods, operations, and procedures on live individuals.

U.S. Patent No. 6,038,488 discloses a catheter simulation device for surgery and interventional radiology procedures. Translation and rotation of the simulated catheter can be tracked and a computerized control system and recording device are employed to provide a programmed procedure which provides a realistic "feel" to a user of a surgical procedure.

WO 99/16352 describes using graphical representations of a surgical instrument and area of the body in which a procedure is being performed to aid an operator using the surgical instrument.

WO 99/39315 describes a vascular access simulation system with a tracking system for monitoring the movements of a simulated catheter needle assembly and a skin traction mechanism. The system receives measurements from the tracking system to update simulation and display of representations of the catheter while providing control signals to a force feedback device to enable the application of force to the catheter needle assembly.

WO 98/03954 describes a system for simulating operating conditions during minimally invasive surgical procedures. Data regarding the movements of a simulated surgical instrument are interpolated by a computer processor, which utilizes a database of information representing a patient's internal landscape to create a computer model of the internal landscape of the patient.

U.S. Patent No, 6,106,301 describes a radiology interface apparatus and peripherals, such as mock medical instruments, for simulating performance of a medical procedure on a virtual patient. The interface measures manipulations of system peripherals and transfers these measurements via a processor to a medical procedure simulation system.

Summary of the Invention

There is a need to have a highly realistic simulation environment for training and pretreatment planning of image-guided, medical procedures such as vascular catheterization, angioplasty, embolotherapy, drug infusion therapy and stent and coil deployment.

This invention is designed to assist physicians in their training and in preplanning of diagnostic and therapeutic procedures performed in the vascular cardiovascular catheterization laboratory. In addition to providing realistic visual feedback and interacting with essential devices, such as are found in a cardiovascular catheterization laboratory, the simulator also provides active

haptic force and tactile feedback components to enhance the total hand-eye coordinated experiences encountered by physicians during actual interventional procedures. To simulate various types of procedures, the invention also provides a novel solution to easily configure or customize the training or pretreatment planning environment to meet the needs of the user or trainer.

In one aspect, the invention provides a system for simulating the movement of a medical device in a body cavity or lumen of a patient. The system comprises a medical device comprising a first end for manipulation by a user and a portion comprising a second end insertable into a simulated body cavity or body lumen in a manikin. The manikin comprises an interface for receiving the portion comprising the second end and for interfacing with the simulated body cavity or lumen. The manikin further comprises a directional force feedback mechanism for exerting a directional force on the medical device in response to a feedback signal.

Preferably, the directional force feedback mechanism provides resistance to forward motion but enables free reverse motion in response to the feedback signal. In one aspect, the directional force feedback mechanism comprises a rolling element coupled to the portion of the medical device comprising the second end. An internal surface of the simulated cavity or lumen in the manikin comprises an oblique slot for receiving the rolling element. In response to a feedback signal, forward movement of the second end will cause the rolling element to be received by the slot, thereby causing resistance to further forward motion. A motor, such as a servo motor, can be used to control movement of the rolling element.

In another aspect, the system further comprises a tactile feedback mechanism which can provide continuous vibrational feedback to a user holding the medical device. Tactile feedback can be provided through a continuously rotating motor in communication with the portion of the medical device comprising the second end. The tactile feedback mechanism can simulate such parameters as blood flow, respiration and the like.

Preferably, the position of at least the second end of the medical device relative the simulated body cavity or lumen is continuously tracked. In one aspect, the medical device comprises an encoder for tracking the translation of the device and an encoder for tracking the rotation of the device. In another aspect, the system comprises a tracking unit comprising a light source, a signal processing circuit, and one or more optical sensors which are placed within the interface. Light from the light source reflects on the device when it is inserted into the interface and reflected light from the device is received by the one or more optical sensors of the tracking system, enabling the movement of the device to be tracked. In response to detection of changes in reflected light, the system will simulate movement of the device in real-time on a user display.

In one aspect, two optical sensors are provided which lie in two different planes which are perpendicular to each other. In another aspect, the tracking unit is configured in the form of a rail along which the device can move.

More than one medical device can be inserted into the interface and the position of each medical device can be independently monitored. Suitable medical devices for use with the system include, but are not limited to: a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof.

In one aspect, the system comprises a table on which the manikin is placed. The table can comprise a processor connectable to the network. Additional ancillary equipment can include, but are not limited to, foot and hand activation switches, radioopaque contrast dye injectors, hand operated balloon inflation devices, and monitors displaying various simulated electrophysiological parameters.

The system comprises at least one first user device connectable to the network which comprises a first display interface for displaying a three-dimensional representation of a simulated body cavity or lumen of a patient. Preferably, the first display interface further displays a three-dimensional representation of a medical device corresponding to a medical device which is interfaced with the manikin. The system simulates the movement of the medical device within the simulated body cavity or lumen of the manikin in real-time on the display, when a first user manipulates the medical device interfaced with the manikin. For example, the system can be used to simulate the movement of a catheter through a blood vessel (e.g., such as a blood vessel in the heart or brain or another organ). In one aspect, the system further simulates deformation of the body cavity or lumen by the medical device.

The system also can comprise a simulated scanning display for displaying a two-dimensional image of the simulated body cavity or lumen. In one aspect, the scanning display is part of a simulated scanning device. For example, the simulated scanning device can simulate an x-ray imaging system. Both the simulated scanning device and scanning display can be coupled to a movable C-arm within scanning distance of the manikin.

To enhance the realism of the simulation, a re-configurable control panel (e.g., a touch screen) can be provided for performing one or more of: image acquisition selection; image display; manipulating a table on which the manikin is placed; manipulating the position of a simulated scanning device relative to the manikin; and control of one or more shutter devices for limiting a field

of view of a scanning device placed within scanning distance of the manikin. The system also can comprise at least one foot-activation switch for activating or collimating the simulated scanning device, image display and/or for controlling table movement.

The system can be adapted for use by multiple users, for example, as part of a training environment. In one aspect, the system comprises a monitoring station comprising a second user device connectable to the network and comprising a second display interface for enabling a second user to monitor the movement of the medical device within the simulated body cavity or lumen. Preferably, the second display interface displays selectable options (e.g., a drop down menu, action buttons, check buttons, radio buttons, dialog boxes, command lines and the like), enabling the second user to select or change one or more anatomical and/or physiological parameters of the simulated body cavity or lumen. Selection of a selectable option causes the three-dimensional image of the simulated body cavity or lumen displayed to the first user to change to reflect the changed anatomical and/or physiological parameters selected by the second user.

In one aspect, the first user display interface provides access to a database and in response to this accessing, the system displays an image and/or medical data of a patient on the first user display interface. In another aspect, the second user display interface provides access to the database and the system displays an image and/or medical data on the second user display interface. In a further aspect, the second user display interface provides a selectable option enabling a second user to display the image which is displayed on the second user display interface, on the first user's display interface.

The invention additionally provides a syringe for simulating fluid delivery, comprising: a housing defining a lumen comprising an opening for delivering a fluid,
a pushing element for pushing the fluid through the opening, a friction-producing element in communication with the pushing element, and a motor in communication with the friction-producing element and comprising a signal-receiving element. The friction-producing element will cause friction between the pushing element and a surface of the lumen of the housing when the motor is activated. Activation of the motor is responsive to a signal received by the signal-receiving element.

When activated, the motor causes motion of the friction-producing element, causing the friction-producing element to contact the surface of the lumen of the housing. This creates friction between the pushing element and the surface of the lumen and causes resistance to the motion of the pushing element, thus simulating injection of a fluid through a syringe into the body of a patient.

The friction-producing element can comprise one or more rubber pads, each rubber pad being coupled to an arm whose movement is controlled by the motor, e.g., such as through a gear attached to the motor. In one aspect, the amount of friction produced by the friction-producing element is adjusted by controlling a rotation angle of the motor.

The syringe can be used with the system described above. For example, the opening of the syringe can be connectable to a connecting piece having a first end for receiving fluid from the opening and a second end for delivering fluid to a simulated body cavity or body lumen in the manikin, e.g., via the manikin interface.

The invention also provides a method for simulating fluid delivery into a body cavity or lumen of a patient comprising providing a syringe as described above and providing a signal to the syringe, thereby causing friction between the friction producing element and the pushing element. Delivery of fluid to a body cavity or lumen can be viewed in real-time on the screen of a first and/or second user interface.

The invention also provides a balloon-inflating device for simulating deployment of a balloon within a body cavity or lumen of a patient. In one aspect, the device comprises a delivery mechanism for controlling delivery of fluid (e.g., such as air) through the balloon-inflating device to the balloon, a pressure sensor for monitoring pressure of fluid delivered, and an electrical pressure meter for reading pressure determined by the pressure sensor. Preferably, the electrical pressure meter is connectable to a processor and can transmit a signal corresponding to a pressure value to the processor. The balloon inflating device can be used with the system; for example, the system can simulate the deployment of a balloon (e.g., inflation or deflation) within the lumen of a patient; i.e., the system can be used to simulate a balloon angioplasty procedure. .

The system also can be used to simulate other operations of medical devices, such as a surgical procedure (e.g., such as removal or repair of a tissue structure), injection of a radioopaque isotope and the like.

The invention further provides methods for using the system described above. In one aspect, the invention provides a method for simulating the movement of a medical device in the body cavity or lumen of a patient, comprising: providing a medical device comprising a first end for manipulation by a user and a portion comprising a second end inserted into a simulated body cavity or body lumen in a manikin. The simulated body cavity or lumen in the manikin comprises a directional force feedback mechanism and in response to a feedback signal, the directional force feedback mechanism creates resistance to forward motion of the medical device but allows free reverse motion, allowing a

first user to experience the sensation of using the device in the body of a patient. In a preferred aspect, the user experiences tactile feedback as well as directional feedback.

The first user of the system can access a database of three-dimensional images of body cavities and lumens from a plurality of different patients. For example, the first user can request a representation of a selected image to be displayed on the display interface of his or her user device in response to this accessing. For example, the user can select a suitable hyperlink displayed on the interface, or can input a query into a command line or dialog box, or can select a selectable option provided on the interface in response to the user's accessing the database.

In one aspect, the system also superimposes a three-dimensional representation of the medical device on the representation of the body cavity or lumen. Preferably, the system simulates the movement of the medical device within the body cavity or lumen in real-time on the display interface as the user manipulates the medical device which is interfaced with the manikin. More preferably, the system also simulates deformation of the body cavity or lumen as the first user simulates navigating and/or deploying the medical device. The user can experience one or more simulated operations of the device, such as a surgical procedure, injection of a radioopaque dye, balloon deployment, and the like.

The first user can manipulate a plurality of medical devices using the interface of the manikin. In response, the system will simulate the movement of each of these devices on the first user's display interface. For example, the system can simulate the can simulate navigating a first catheter to a target region of the body, then a balloon catheter, and then positioning a balloon deployment device (e.g., such as the one described above) in proximity to the balloon catheter to inflate or deflate the balloon.

In another aspect, the system also simulates inserting a stent catheter, navigating the stent catheter to the target region, and using the balloon deployed by the balloon catheter to deploy the stent. In a further aspect, the system simulates coil embolization in a body cavity or lumen of a patient. As a first user interacts with the manikin by inserting a catheter, guidewire, and coil wire into the simulated body cavity or lumen, the system simulates movement of each of these devices in the simulated body cavity or lumen on the first user's display interface. A selectable option on a control interface provided as part of the system (e.g., a re-configurable control panel or touch screen) provides the user with a selectable option for detaching the coil from the coil wire. When the user selects the selectable option, the coil is released from the coil wire in the manikin and on the screen of the first user's display interface.

A second user also can interact with the first user by using the monitoring station described above. For example, the second user can display a particular image selected by the second user from the database on the first user's display interface. The second user can alter parameters of the simulation displayed to the first user, for example, as part of a training exercise, to document the progress of one or more first users, and/or to introduce procedural variables that can be used to test or evaluate the response and decision-making abilities of one or more first users.

In a particularly preferred aspect, the system is configured to resemble a cardiovascular catheterization laboratory where interventional radiology procedures are performed. A first user can interactively manipulate therapeutic catheters, guidewires and other medical devices in real-time while viewing patient-specific medical image data sets in a manner similar to that encountered in a clinical procedure.

Brief Description of the Figures

The objects and features of the invention can be better understood with reference to the following detailed description and accompanying drawings.

Figure 1 is the block diagram of a simulation system according to one aspect of the invention.

Figure 2 illustrates a perspective view of a system according to the invention. A simulated patient (6) or manikin houses tracking and force feedback assemblies. Simulated medical devices are introduced into the simulated patient via a user interface box embedded within the patient/manikin (e.g.. through the groin or axillary area, in the case of a simulated catheterization lab). A first user (1) navigating and/or deploying simulated devices can be monitored by a second user (19) according to one aspect of the invention.

Figure 3 is a block diagram showing various components of a system processor according to one aspect of the invention.

Figure 4 is a block diagram showing various system inputs according one aspect of the invention, such as touch screens, footswitches, syringes, C-arm, hand-operated balloon device, feedback structures, and their connections with the system processor.

Figure 5A illustrates the mechanical structure of a tracking system and active force feedback structure according to one aspect of the invention. More than one set of catheters and guidewires can be used in a given simulation. The translation and rotation of each device are measured using incremental encoders. For example, encoder A and encoder B measure the translation and rotation of

a catheter, respectively. Figure 5B is a block diagram illustrating components of the tracking system and active force feedback system and their interactions with the system processor.

Figure 6A illustrates a different tracking system according to one aspect of the invention comprising one or more optical sensors. Figure 6B shows a tracking unit and catheter device configured as a loop which can be used to simulate pushing, pulling, or twisting.

Figures 7A and B show more detailed views of a directional force feedback mechanism according to one aspect of the invention. As shown in Figure 7A, a wheel coupled to a motor directs forward movement of a simulated catheter through a shutter connected to the simulate catheter. Forward and downward motion of the shutter, forces a rolling element coupled to the catheter into an oblique slot which creates resistance to further forward motion. A discontinuously rotating hand provides a sensation of vibration. Figure 7B shows a close up of the rolling element (e.g., a shaft) and a cross-section through the oblique slot.

Figures 8A1-3 and B shows the structure of a simulated syringe with a force feedback mechanism according to one aspect of the invention. Figure 8A shows a cross-section through the longitudinal axis of the device while Figure 8B shows a cross-section through the tranverse axis of the device.

Figure 9 shows a simulated hand-operated balloon-inflating device according to one aspect of the invention. A pressure sensor is used to measure the pressure of inflation of a balloon attached to a catheter. The sensor signal is processed and transmitted to the system processor. A user can read the pressure value from a display monitor or from a piezometer as shown in the upper portion of the Figure. A user also can feel pressure transmitted back from a catheter port from the balloon during the inflation process.

Figures 10A-D show re-configurable control panels according to different aspects of the invention.

Figure 11 shows a scaled-down simulation system according to one aspect of the invention.

Figure 12 shows a desktop simulation system for pretreatment planning comprising a re-configurable control panel.

Figure 13 is a flow chart showing the steps of a simulation process according to one aspect of the invention.

Figure 14 illustrates the time/realism requirements of a simulation system according to the invention.

Figure 15 shows a physical model of vascular data and device data which can be inputted into a system processor according to the invention.

Figure 16 illustrates creation of a physical model of a body cavity or blood vessel according to one aspect of the invention.

Detailed Description

The invention provides a system for the simulation of image-guided medical procedures and methods of using the same. The system can be used for training and certification, pre-treatment planning, as well therapeutic device design, development and evaluation.

Definitions

The following definitions are provided for specific terms which are used in the following written description.

As used herein, "coupled to" refers to direct or indirect coupling of one element of a system to another. An element may be removably coupled or permanently coupled to another element of the system.

As used herein, "within scanning distance" refers to a distance which is close enough to the manikin to permit display of an image of the simulated body cavity or lumen on the scanning display of the system.

As used herein, "a re-configurable control panel" refers to a display interface comprising one or more selectable options (e.g., in the form of action buttons, radio buttons, check buttons, drop-down menus, and the like) which can be selected by a user and which can direct the system to perform operation(s). Preferably, the one or more options can be selected by touch. The control panel can be modified by a user (e.g., by implementing a system program which alters the display, causing it to display different selectable options) thereby "re-configuring" the control panel.

As used herein, "providing access to a database" refers to providing a selectable option on the display of a user device which, when selected, causes the system to display images or data stored within the database, or causes one or more links to be displayed which, when selected, causes the

system to display the images or data. In one aspect, the system displays images or data, or links to images or data, in response to a query of the system by a user. In one aspect, the display interface provides a "query input field" into which the user can input a query and the selectable option is an action button for transmitting the query to the system.

As used herein, the term "in communication with" refers to the ability of a system or component of a system to receive input data from another system or component of a system and to provide an output response in response to the input data. "Output" may be in the form of data or may be in the form of an action taken by the system or component of the system.

As used herein, "deployment of a balloon" refers to either inflation or deflation of the balloon.

As used herein, a pathology "affecting the structure of the body cavity or lumen" is one which measurably alters at least one physical property of the body cavity or lumen..

As used herein, "a physical property" refers to a property which relates to the structure or anatomy of a body cavity or lumen which is measurable, generally without the aid of a labeled molecular probe; for example, physical properties of a blood vessel include, but are not limited to: elasticity, thickness, strength of ventricular contractions, vascular resistance, fluid volume, cardiac output, myocardial contractility, and other related parameters.

As used herein, "a volume image" is a stack of two-dimensional (2D) images (e.g., of a body cavity or lumen) oriented in an axial direction.

As used herein, a device for "accessing a body cavity or lumen" refers to a device which can be maneuvered in the body cavity or lumen. "Maneuvering" refers to the ability of at least about 50% of the external surface of the device to fit within a cavity or lumen while retaining rotational or forward translational freedom of movement.

As used herein, an "interventional medical device" includes a device for treatment (e.g., stents, stent-grafts, balloons, coils, drug delivery devices), for diagnosis (e.g., imaging probes), and for placement of other medical devices (e.g., guidewires). Some devices, such as catheters, can have multiple functions. In general, the terms "an interventional medical device" and "device for accessing a body cavity or lumen" are used interchangeably.

As used herein, a "knowledge base " is a data structure comprising facts and rules relating to a subject; for example, a "vascular properties knowledge base" is a data structure comprising facts relating to properties of blood vessels, such as elasticity, deformation, tissue and cellular properties,

blood flow, and the like and rules for correlating facts relating to vascular properties to interactions with one or medical devices.

As used herein, a "rule" in a knowledge base refers to a statement associated with a certainty factor. Rules are generally established by interviewing human experts or by obtaining data from databases or other knowledge bases.

As used herein, an "expert system" comprises a program for applying the rules of one or more knowledge bases to data provided to, or stored within the knowledge base(s), thereby enabling the knowledge base(s) to be queried and to grow. Preferably, an expert system comprises an inference engine which enables the system to manipulate input data from a user to arrive at one or more possible answers to a question by a user. More preferably, an expert system also comprises a cache or dynamic memory for storing the current state of any active rule along with facts relating to premises on which the rule is based.

As used herein, a system which "simulates a path representing at least a portion of a body cavity or lumen" is a system which displays a three-dimensional representation of the internal surface of the at least a portion of the body cavity or lumen on the interface of a user device in communication with the system.

As used herein, to "determine the best fit between the geometry of the device and the geometry of the path" refers to displaying a representation of at least a portion of the device and simulating its placement within at least a portion of the body cavity or lumen.

As used herein, a "device parameter" refers to a physical property of a device, e.g., such as flexibility, memory, material, shape, and the like.

As used herein, "a physical model of a device" is a combination of a recommended geometrical model, topology, and material. It is also the basis for making the first design of a medical device based on patient-specific data.

As used herein, a "software suite" refers to a plurality of interacting programs for communicating with an operating system.

As used herein, "clinical data" refers to physical, anatomical, and/or physiological data acquired by medical image modalities such as X-ray, MRI, CT, US, angiography, video camera, or by direct physical and/or electronic measurements.

As used herein, "a best fit" between a simulated path for a simulated body cavity or lumen and a simulated medical device refers to one which requires the minimum amount of deformation in the simulated surgical process that takes into consideration the patient-specific vasculature and composite materials of the device.

As used herein, an "FEM engine" refers to a program or set of programs for performing finite element analysis focusing on vasculature finite element models and analysis of the interaction between vasculature models and devices.

Intervention Simulation System

Figure 1 is a block diagram of a simulation system according to one aspect of the invention. Input into the system executes a particular simulation to be enacted. Generally, a simulation includes images of a patient and also can include a display of patient-specific information (e.g., such as clinical information and medical history). The patient images can be obtained from a database of patient-specific images or images relating to a population of demographically similar patients (e.g., such as patients sharing a pathology). Preferably, the system also accesses data relating to various interventional devices. For example, the system can include data files relating to the shape and physical properties of one or more medical devices. Preferably, the simulation system also includes a manikin (6) (i.e., representing a patient) for interfacing with one or more simulated medical devices (see, e.g., as shown in Figure 2).

Users interact with the simulation system by observing various rendered displays (2), such as fluoroscopic images of blood vessels, and manipulate the one or more simulated devices in response to data received by these display (2). The invention can simulate the anatomy of a specific patient on which the one or more devices will be used.

Simulated Patient Interface

In one aspect, the intervention simulation system comprises a medical device with a first end for manipulation by a user and a portion comprising a second end which is insertable into a simulated body cavity or body lumen in a simulated patient interface. Preferably, the simulated patient interface is part of a manikin (6) which simulates the physical features of a human patient. The manikin (6) comprises an interface (5) for receiving the portion comprising the second end and for interfacing with a simulated body cavity or lumen within the manikin.

The interface also comprises a directional force feedback mechanism for exerting a directional force on the candidate medical device in response to a feedback signal received by the

force feedback mechanism. This provides a user with a feeling that he/she is interacting with a real patient. Preferably, the directional force feedback mechanism provides resistance to forward motion but enables reverse motion in response to the feedback signal. The medical device can be one which is commercially available, a device being tested for use or not otherwise commercially available, or can be a candidate device based on a simulated design selected to suit the characteristics of a particular patient. Methods and systems for designing customized medical devices are disclosed in U.S. Provisional Application Serial No. 60/273,734, filed March 6, 2001.

As shown in Figures 7A and B, in one aspect, the directional force feedback mechanism comprises a rolling element (e.g., such as a shaft) coupled to the portion of the candidate device comprising the second end. An internal surface of the simulated cavity or lumen in the manikin in turn comprises an oblique slot for receiving the rolling element. In response to a feedback signal, forward movement of the second end causes the rolling element to be received by the slot, causing resistance to further forward motion. Preferably, a motor, such as a servo motor, controls movement of the rolling element. This embodiment is shown in more detail in Figure 7A. When a force feedback control signal is generated, the servo motor rotates clockwise, causing a wheel to rotate, pushing a shutter forward and downward. The forward and downward movement of the shutter pushes the rolling element down into the slot. Because of friction between the slot and the rolling element, the rolling element moves upward along the slot, and any further forward movement is resisted. If the user wishes to pull back the device, the rolling element will move downward and can be released from the slot.

In a most preferred embodiment, the interface comprises both a directional force feedback mechanism and a tactile feedback mechanism. The tactile feedback mechanism provides vibrational feedback to a user holding the candidate medical device. In one aspect, continuous vibrational feedback is provided through a continuously rotating motor (e.g., such as the servo motor) in communication with the portion of the device comprising the second end. A discontinuously rotating motor controlling the movement of a hand (see, e.g., Figure 7A) also can be used to simulate intermittent forces experienced by a body cavity or lumen. For example, in a clinical situation, when a catheter is inserted into the cardiovascular system, cardiovascular function and activity may cause the catheter to vibrate. The servo motor and the rotating hand are designed to simulate this kind of vibration. The servo motor rotates continuously and but has an adjustable rotating frequency. . The rotating hand pushes the catheter discontinuously, i.e., simulating blood flow and respiration.

Haptic "display" serves at least two purposes in the intervention simulator: kinesthetic and cognitive. First, it provides the sensation of movement to the user and therefore it greatly enhances

surgical performance. Second, it is used to enable a user to learn to distinguish between tissues by testing their mechanical properties. Deformation models are used to compute the effect of force on the biomechanics of an interventional device and on the deformation of a cavity or lumen through which the device is navigating and/or being deployed, and feedback signals to the force feedback and tactile feedback mechanisms can be used to mimic actual forces that might be experienced during an interventional procedure.

However, although the system is capable of providing physically meaningful forces that realistically mimic those encountered during an interventional procedure, there may be instances where a less realistic simulation is satisfactory. For example, a user may want to feel that he or she has reached an obstruction during catheterization. However, the user may not need to experience all the various contacts he or she could feel while maneuvering a catheter prior to experiencing a single large resistance. The present invention provides a mechanism to stop a user from advancing past an obstruction and yet permits the user to pull back a simulated device.

The manikin interface can be encased in a housing comprising one or more openings for receiving medical devices, and means for interfacing with tracking unit(s), feedback mechanism(s) and a system processor (described further below). Additional devices such as syringes and balloon inflating devices can be provided as part of the interface, e.g., simulating balloon angioplasty proceedings).

The interface housing can be displaceable for some distance from the manikin itself or can project from the manikin (e.g., being an integral part of the manikin). To further enhance realism, only the opening(s) of the housing may visible from the manikin (e.g., the interface "housing" can be part of the manikin). Preferably, the interface is an embedded system as shown in Figure 2, with openings into areas of the manikin simulating areas of medical intervention.

System Input Devices

The simulation system can obtain input of various types to more closely mimic an intervention procedure. For example, as shown in Figure 1, input to the simulator can consist of patient medical history and diagnostic data including, but not limited to, data obtained from X-ray, MRI, MRA, CT or ultrasound images. Data can relate to a specific patient, e.g., where a user is training to perform a procedure on a specific patient using a customized device. Alternatively, data can relate to a "symbolic patient", for example, representing a particular demographic group of closely related patients, such as patients having a type of pathology.

Figure 2 shows an example of various system inputs that can be provided. The simulated patient (6) in the Figure is a manikin that also houses the tracking and force feedback assemblies. A physician (1) simulates navigation of a catheter by manipulating catheters and guidewires (5). These catheters and guidewires are inserted into the manikin at the manikin interface. One or more monitors (2) can be used to display simulated fluoroscopic and vascular images simulating the internal anatomy of a patient represented by the manikin. In one aspect, 2-D fluoroscopic views are displayed at the same time that 3D geometric models are displayed by system user interfaces. Preferably, the user has the option to adjust fluoroscopic images by one or more of zooming, collimation, rotation, and the like. In combination with 3D volume-rendered images generated using display interfaces described further below, a user can view the vasculature from various positions or angles along x-, y-, and x- axes. This option can be of major value in pre-treatment planning, since a physician can use the system to evaluate different treatment approaches prior to performing actual intervention in a patient.

A simulated scanning device (4) additionally can be provided, e.g., in the form of a mock C-arm equipped with an x-ray emitter. Preferably, the mock C-arm can move along the long side of an operating table (8) on which the patient/manikin is placed and can rotate around the table to simulate capturing a patient's images at various lateral and angular positions.

For example, as shown in Figure 2, two footswitches (7) can be used to simulate activation of a simulated x-ray device as well as vascular image acquisition and storage. In response to this activation, one or more monitors (2) simulate fluoroscopic images obtained. A footswitch is preferred for scanning and image processing, since user(s) generally have their hands occupied with other equipment, in actual practice

Preferably, the system provides a re-configurable control panel (9) (e.g., a touch screen) to enable a user to simulate patient table manipulation, vascular image acquisition selection and display, and the use of shutter devices to limit the extent of the field of view provided by a scanning device (4). The panel also can be used to implement functions such as machine-activated radioopaque dye injection (e.g., activating the simulated syringe) and/or deployment of a balloon via a balloon-inflating device (18) interfaced with the manikin.

Figures 10A –D show re-configurable control panels according to different aspects of the invention. Preferably, the display is programmable and has a large storage area for bitmaps, display lists, and screens. Users can easily set up complex image control panels according to their own requirements. Figure 10A shows the typical controls associated with patient table manipulation. Manipulating these controls result in a corresponding motion of a C-arm that carries a simulated X-

ray emitter. Figure 10B shows controls associated with image acquisition for manipulating the sharpness and clarity of the rendered images. Figure 10C shows controls for machine activated balloon inflation and deflation, and shuttering. Figure 10D shows controls for collecting images for creating a roadmap.

In a preferred aspect, the invention additionally provides one or more interventional devices interfaced with the manikin for simulating common procedures such as an injection, balloon deployment, and/or stent deployment.

In one aspect, therefore, the system comprises a syringe for simulating fluid delivery. The simulation syringe comprises a housing defining a lumen comprising an opening for delivering a fluid, a pushing element for pushing the fluid through the opening, a friction-producing element in communication with the pushing element, and a motor in communication with the friction-producing element which further comprises signal receiving element. The simulation syringe can be interfaced with the manikin and the signal-receiving element preferably receives signals from the system processor, e.g., to execute contrast injection at a particular flow rate and volume.

The friction-producing element will cause friction between the pushing element and a surface of the lumen of the housing when the motor is activated in response to a signal received by the signal-receiving element. When activated, the motor causes motion of the friction-producing element, causing the friction-producing element to contact the surface of the lumen of the housing. This creates friction between the pushing element and the surface of the lumen and causes resistance to the motion of the pushing element, thus simulating injection of a fluid through a syringe into the body of a patient.

The friction-producing element can comprise one or more rubber pads, each rubber pad being coupled to an arm whose movement is controlled by the motor, e.g., such as through a gear attached to the motor. In one aspect, the amount of friction produced by the friction-producing element is adjusted by controlling a rotation angle of the motor.

Figures 8A1-3 and B show the structure of a simulated syringe (3) with force feedback structure according to one aspect of the invention. In the embodiment shown in Figures 8A-B, a servo motor and two arms are installed in front of the pushing element (e.g., a handspike). These two arms are connected through two meshed gears. Gear 1 is installed on the servo motor as is the driver of the motor. When a force feedback signal is communicated to the servo motor, the Gear 1 will contrarotate and Gear2 will rotate clockwise. Arm 1 and Arm 2 splay and the rubber pads on the two arms will touch the wall of the syringe. Because of the friction, the surgeon will feel resistance when

he or she tries to push or pull the pushing element. The value of the friction can be adjusted by controlling the rotation angle of the servo motor. When the servo motor rotates clockwise, the two arms will close and the user can move the handspike freely again.

The simulated syringe (3) can be used to simulate the injection of radioopaque dye, to simulate fluoroscopic imaging, or the delivery of a therapeutic agent or drug. Control parameters such as contrast injection volume and rate can be controlled by a user through a control interface such as a touch screen, enabling a user to choose the rate and total volume of injection. The injection process can be captured, and selected images of the process saved, to provide a roadmap image on a separate monitor.

As discussed above, the manikin also can be interfaced with a balloon-inflating device for simulating such operations as balloon and stent deployment. Figure 9 shows a simulated hand-operated balloon-inflating device. A pressure sensor is used to measure the pressure of a fluid, such as air, being delivered to a balloon catheter, which has been navigated to a target site. The signal of the sensor is processed and transmitted to the system processor through the microprocessor MI. A user is able to read pressure values from a display monitor or from an electrical pressure sensor, such as the piezometer shown in the upper portion of Figure 9. Additionally, the user is able to feel pressure delivered by the balloon-inflating device. Preferably, the inflating device can provide up to about at least 20 Bar of compressed liquid to a balloon.

In one aspect, compressed liquid is provided within a compressed liquid generator in communication with a piston. A user can trigger delivery of compressed fluid from the generator by imparting linear force on the piston, thereby triggering inflation of a balloon. Preferably, the compression stroke is approximately 2 inches and can be delivered when a user twists a handle of the balloon-inflating device, causing a screw bar to force the piston forward. A release button or switch is provided enable rapid release of compressed fluid, thereby triggering deflation of the balloon. In a further aspect, an automatic control system inside the device is used to control the forward or backward movement of a handwheel for controlling the amount of pressure actually delivered to the balloon, in steps of a minimum of 0.01 Bar. Pressure values can be read from a screen of the pressure meter (e.g., such as an LCD screen) or can be displayed on the display of a user device.

Preferably, the system enables a user to program parameters such as maximum pressure delivered to the balloon. In one aspect, the user starts to increase pressure delivered to the balloon by means of a button on a handheld remote control and monitors pressure values on a pressure display. The system may trigger an alarm when balloon pressure increases past a selected threshold. In an

"auto mode" the system analyzes pressure data automatically to automatically adjust pressure and increase/decrease speed of inflation or deflation as appropriate.

Signals from simulated devices such as the simulated syringe and/or hand operated balloon inflation device generally are processed by an A/D converter first and then inputted to the system processor. Preferably, signals from footswitches are digital and inputted directly to the microprocessor and then to the system processor.

The system can include additional input devices to simulate an interventional procedure. For example, one or more monitors can be included to simulate display of electrophysiological signals such as ECG and blood pressure.

The system is designed to allow use by multiple users (see, e.g., Figure 2). For example, a second user (19) can be introduced to alter the simulation parameters that a first user (1) is experiencing. In one aspect, therefore, the system further comprises one or more monitors (13-17) comprising one or more second user display interfaces for a enabling a second user (e.g., a trainer) (19) to monitor a simulation that a first user (1) is experiencing. The second user/trainer (19) is provided with selectable options on the display of his or her user interface to enable the second user (19) to alter or introduce variables (e.g., anatomical or physiological variables) in order to test or evaluate the responses or decision-making abilities of one or more first users (1).

In one aspect, processor interface (13) is used to connect a monitor (15), keyboard (16) and mouse (17) of a first user device to a system processor connectable to the network. In one aspect, the system processor communicates with a microprocessor (M1) which resides inside an operating table which receives the manikin. Using a floppy disk driver (10) and/or CD-ROM drive (12), and/or other memory devices, new patient cases can be loaded into the simulation system. Because the processor is connectable to the internet or intranet, remote observation or training is possible. A user (1 or 19) can upload relevant patient images or other medical data or can upgrade software using the monitor (15), keyboard (16) and mouse (17).

Figure 3 is a block diagram highlighting the features of the system processor, according to one aspect of the invention. In the aspect shown in Figure 2, the processor is a CPU installed inside a patient table (8) which controls data and control flow among various system components such as a hard drive, memory, display monitors, manikin interface, and one or more simulated medical devices.

Figure 4 is a block diagram showing interactions between the system processor and various system inputs according to one aspect of the invention. A microprocessor (MI) is used for data acquisition. Tracking information from an optical tracking unit in optical communication with one or

more simulated medical devices is provided to the M1 through a signal processing circuit. A mock C-Arm moves in response to a control signal from a touch screen connected to the microprocessor through a serial port. Preferably, the control signal is processed by the microprocessor prior to being received by the C-arm.

Preferably, manipulations of a device by a user in an interface provided in the manikin are coordinated with a simulation of the device on the user display, such that motion of the device in the manikin is simulated on the user display in real-time.

Therefore, in one aspect, the simulation device provides a mechanism to continuously track a position of at least the second end of the medical device relative to the manikin. For example, the system can comprise one or more encoders for tracking translation and/or rotation of the device (see, e.g., Figures 5A and B). Figure 5B is a block diagram illustrating the components of the tracking system and the active force feedback mechanism. Using rolling spherical objects coupled to a simulated catheter and guidewire, respectively, four incremental encoders can pick up the motions of the simulated devices. The rolling elements also serve as part of the directional force feedback mechanism described above.

In a currently preferred aspect, as shown in Figures 6A and B, the system comprises a tracking unit which tracks the movement of the candidate medical device. The tracking system comprises a light source (e.g., a point light source), a signal processing circuit, and one or more optical sensors, and is placed within the interface in optical communication with the device and the simulated cavity or lumen through which the device is being navigated. The candidate device will reflect light to it from the light source and reflected light will be received by the optical sensor(s). Changes in reflected light picked up from the sensor(s) indicate movement of the candidate device as a result of manipulation.

In one aspect, two optical sensors are provided within the tracking unit, each perpendicular to the other.

As shown in Figure 6A, the tracking unit can be in the form of a rail along which the device can move. Alternatively, the simulated interventional device can be looped around the tracking device and can be manipulated by pushing, pulling, and/or twisting the loop. Preferably, tracking systems enable the intervention system to independently track the movement of two or more medical devices, for example, a catheter and guidewire.

Being an embedded system with detachable components, the simulation system is flexible and can be easily configured to suit the customized needs of its users. Figure 11 shows a possible

configuration that reduces the size of simulation system to one which can be placed on a normal desktop. Figure 12 is a desktop system intended for pretreatment planning by interventional radiologists.

System Processor

The intervention simulation system further comprises at least one first user device (e.g., a computer or wireless device connectable to the network) comprising a graphical user interface and connectable to a system processor and/or the network. Preferably, the processor comprises one or more programs for generating a geometric model of a body cavity or lumen of a patient from stored or collected volume-rendered images obtained from one or more patients. In one aspect, the user can access a database of such images using the user interface, either by inputting text into a command box or dialog box and implementing a search function of the system or by selecting one or more selectable options reflecting files and/or images stored in the database (e.g., a hyperlink designated by the name of the file).

The system generally operates by means of a software suite that operates on a general purpose computer such as a PC or IBM-compatible device. Preferably, the system comprises a processor (e.g., as CPU), memory, graphics adaptor, printer controller, hard disk and controller, mouse controller, and the like. The processor should comprise a minimum of about 8 MB of RAM. Preferably, the first user display interface is part of a monitor which is connected to a keyboard, mouse, and, optionally, printer and/or scanning device. The software suite of the system comprises a program (e.g., a C language program) that controls the system's user interface and data files, e.g., providing one or more of search functions, computation functions, and relationship-determining functions. In a preferred aspect, the system comprises a geometric modeling system for modeling a three-dimensional representation of a body lumen or cavity; a device modeling system for modeling a three-dimensional representation of one or more medical dev ices, and at least one knowledge base for modeling interactions between a simulated body cavity or lumen and a simulated medical device.

Geometric Modeling System

In one aspect, optical data relating to the internal contours of a body cavity or lumen are obtained and provided to the intervention simulation system. The optical data can be displayed directly on one or more user interfaces or can be stored in a system database as described above. Because the system user devices and processors are connectable to the network, patient data also can be accessed from remote databases.

To generate a volume-image, a stack of two-dimensional (2D) images is collected by a scanning device in an axial direction and is used to form a three-dimensional (3D) structure (see, e.g., as shown in Figures 3A and 3B). Almost all medical scanners can produce these axial images or can produce images that can be converted easily to axial images. Suitable scanning devices include, but are not limited to, x-ray devices, magnetic resonance imaging (MRI) devices, ultrasound (US) devices, computerized tomography (CT) devices, rotational angiography devices, gadolinium-enhanced MR angiograph devices, or other imaging modalities. For example, rotational CT scanners capture patient data in the form of projection images. By using a Filtered Back Projection technique or Arithmetic Reconstruction Technique (ART), volumetric images can be constructed.

The system may be directly connected to the output of one or more scanning devices, e.g., collecting optical data from such devices as these are acquired. However, in another aspect, the system may include a means for extracting features from individual scanned images (e.g., communicated to the system through a scanner or provided as a pdf file) to construct a 3D volume image. The geometric modeling arm of the system can be implemented remotely by a user to determine one or more of: the geometry/topology of the body cavity or lumen, measurements relating to any pathological features of the body cavity or lumen, and such parameters as tissue wall thickness, elasticity and the like.

In creating a geometric model of a body cavity or lumen (e.g., such as a blood vessel), a user of the system (e.g., a biomedical professional with knowledge of human anatomy and pathology) performs image processing tasks on a plurality of scanned images to create geometrical structures and a topology which corresponds to the contours of a body cavity or lumen belonging to a patient being analyzed.

Volume rendering techniques such as ray casting and projection techniques have traditionally been used in the visualization of volume images. Ray casting methods shoot rays through a volume object from each pixel in an image and employ algorithms that trilinearly interpolates samples along each ray, providing complex shading calculations and color assignments at the sample points which are then accumulated into final pixel colors (see, e.g., Kaufman, In *Volume Rendering*, IEEE Computer Science Press, Las Alamitos, CA, 1990). Real-time volume rendering with hardware texture mapping (e.g., SGI) for UNIX platform or with board card (e.g., Mitsubishi VolumePro) for PC platforms are commercially available.

Commercially available image processing tools, such as Photoshop™ can be used to manually draw out the shape of the structure from each scanned image. Various imaging-processing tasks, as

are known in the art, can be performed by the system; for example, segmentation can be used. Several improved algorithms using iso-surfacing or volume-rendering techniques to visualize vascular trees also can be used and have been described in Ehricke, et al., *Computer & Graphics 18(3)*: 395-406, 1994; Cline, et al., In *Magnetic Resonance Imaging (Pergamon Press) 7*: 45-54, 1989; and Puig, et al., *Proc. Of Visualization '97*, pp 443-446, for example.

Projection-originated methods reconstruct 3D geometries from two or more images (See, e.g., Solbach, et al., *Computer Biomedical Research 27(3)*: 178-198, 1994; Nguyen and Sklansky, *IEEE Transactions on Medical Imaging 13(3)*: 178-198, 1994; Longuet-Higgens, *Nature 293(10)*: 133-135, 1981). Thinning methods such as "active-contour", "medial axis transformation", and "simulated annealing", and the like, can be employed to determine information in projection planes (see, e.g., Kass, et al., *International Journal of Computer Vision 1*: 321-331, 1987; Lee, et al., *CVGIP: Graphical Models and Image Processing 56(6)*: 462-478, 1994; Arcelli and di Baja, *Image and Vision Computing 11(2)*: 163-173, 1993; Pellot, et al., *IEEE Transactions Medical Imaging 13(1)*: 48-60, 1994; Brandt and Algazi, *CVGIP: Image Understanding 55(3)*: 329-337, 1992). The advantage of projective reconstruction lies in its capability to handle tiny tube-like systems such as vascular, neural and lymphatic vessels that could be lost with iso-surfacing algorithms.

"Piece-by-piece cylinder representation" or "generalized cylinder representation" is widely used in vascular modeling (see, e.g., Brown et al., *Proceedings of EUROGRAPHY '87*, pp 113-124;Barillot et al., *IEEE Transactions on Computer Graphics and Applications*, December 1985, pp 13-19). Polygonal tessellation, e.g., triangulation, also can be applied to model 3D tube-like shapes as is known in the art (see, e.g., Sederberg, et al., *International Journal on Computational Geometry and Applications 8(4)*: 389-406; Choi and Park, *Visual Computer 10*: 372-387, 1994). Ferley, et al., *Computer Graphics Forum 165(5)*: 283-293, 1997, additionally describes an implicit surface method for reconstruction of branching shapes.

Accurate modeling of a 3D vascular network relies on good representations of vascular segments and bifurcations. Ideally, a vascular model should be visually smooth and the detail of the display should be adaptable to fit application requirements. In one aspect, a constructive approach is used to model visually smooth vascular networks. In this approach, vascular segments are modeled using sweeping operations while vascular bifurcations can be modeled using blending operations (i.e., sweeping plus hole-filling operations) (Gregory and Zhou, *Computer Aided Geometric Design 11*: 391-410, 1994; Ye, et al., *Computer Aided Geometric Design 27*: 875-885, 1995). Based on GC conditions for boundaries and cross-boundary derivatives (see, e.g., Schreiner and Buxbaum, *IEEE Transactions on Biomedical Engineering 40(5)*: 482-491, 1993), constructive algorithms for

segmental sweeping and bifurcation blending can be designed as described in Cai et al., "Constructive Algorithms for GC1 Generation of Vascular Network," Submitted to IEEE Biomedical Engineering, March 2001. See, as shown in Figures 5 and 6.

Yet another method of obtaining a volume model or a geometric model of a body cavity or lumen is the technique of volumetric meshing. Meshes which represent a 3D or volumetric form can be generated from scanned images using a standard Windows operating system such as NT. Software for generating 3D mesh images are commercially and publicly available. Sources for such software are described at http://www-users.informatik.rwth-aachen.de/~roberts/software.html#Commercial, and include, for example, Altair®HyperMesh®5.0 (available from Altair Engineering, Inc., Maplelawn, Troy, MI 48084).

In a preferred aspect, a volume image of a blood vessel is obtained to construct a physical or geometric model which comprises information relating to both shape and material of tissue forming the blood vessel. Generally, construction of geometric models entail dividing a 3D modeling process into a series of 2D cross-sectional segmentation operations from which the 3D surface of the structure is reconstructed. An image processor is used to draw out the shape of the desired vascular structure from each image. Segmentation methods relying on intensity thresholding or region-growing can be used, as are known in the art, to facilitate the process (see, e.g., Wang, et al., *IEEE Engineering in Medicine and Biology*, November/December 1999, pp 33-39; Moore, et al., *J. Biomechanics 31*: 179-184, 1998). Finite element modeling also can be used for blood flow modeling, as described in, for example, Taylor, et al., *Computer Methods in Applied Mechanics and Engineering 158*: 155-196; Hughes et al., *Computer Methods in Applied Mechanics and Engineering 73(2)*: 173-189, 1989; Shephard and Georges, *Int. J. Numerical Methods in Engineering 32*: 709-749, 1991.

Surface sweeping is a powerful tool for creating tube-like shapes, i.e., simulating blood vessels. The sweeping operation requires a smooth trajectory and cross-sectional shapes. To form a tube-like surface, a closed cross-sectional contour must be used. A cubic Bézier curve is used to represent the central trajectory or path. With $\gamma(t)$ representing any of G^1 paths, a local coordinate system (T (t), N(t), B(t)) can be defined along the curve (see, e.g., Figure 5). This triplet (T (t), N(t), B(t)), also known as a "Frenet frame", is the tangent, normal and bi-normal defined along the trajectory of the curve. Assuming $r(t)$ is a contour function defined in the cross-sectional plane perpendicular to the curve at a given point along the trajectory, the sweeping surface can be represented as

$$\Gamma(t, \theta) = \gamma(t) + r(t)\ (\cos\theta\, \mathrm{N}(t) + \sin\theta\, \mathrm{B}(t)),$$

as described by Piegl and Tiller, In T*he NURBS Book*, Springer, Berlin, 1995, where θ is the cross-sectional angle and $t \in [0,1]$ is a parameter defined along the curve. A bi-cubic Bézier form for the

sweeping tube can therefore be developed using a tensor-product operation (see, e.g., Piegl and Tiller, 1995, *supra*).

To model bifurcation, the same sweeping operation can be applied. In order to avoid self-intersection, only half of the tubular surface can be used (Figure 6). This, however, leads to missing two triangular patches (front and back) at the joint. Bifurcation modeling therefore requires triangular hole filling. An analytic approach described in Gregory and Zhou, *Computer Aided Geometric Design 11:* 391-410, 1994, can be used to fill triangular holes with given neighboring surfaces. To generate G^1 smooth bifurcations, however, additional modifications of hole boundaries and hence the surrounding surfaces are desirable. The procedures for bifurcation modeling are summarized as follows:

(i) A bifurcation is first generated by sweeping three semi-tubular surfaces in bi-cubic Bézier form.

(ii) Two triangular holes are formed by three surrounding semi-tubular surfaces. Each hole is initially "filled" with three bi-cubic Bézier patches using the method described in Gregory and Zhou, 1994, *supra*.

(iii) The boundaries of the semi-tubular surfaces are changed to quintic Bézier form. The modifications are determined from the cross-boundary tangential continuity, twist-compatibility and unique existence of tangent planes at hole comers.

(iv) Three semi-tubular surfaces are then degree-elevated into quintic Bézier patches and modified based on the new hole boundaries. The next row of control points of the hole boundaries are modified accordingly to ensure that the semi-tubular surfaces having cubic cross-boundary derivatives along the hole boundaries.

(v) The vector-valued cross-boundary derivative in a quintic form along the hole boundaries is generated for the filling hole patches.

(vi) The hole boundaries are split into two at the middle point of the parameter, so are the associated vector-valued cross-boundary derivatives. The star-lines and their associated vector-valued cross-boundary derivatives are degree-elevated to quintic as well.

(vii) Three final filling rectangular patches are generated based on the updated starlines, split hole boundaries, and the vector-valued cross-boundary derivatives along the star-lines and the split hole boundaries. The remaining 3x3 interior control points are determined by taking a Coons-Boolean sum approach as described in Ye, *Computer Aided Design 27:* 875-885; 1995.

From the segmented medical images, a central line model of a vasculature can be constructed. This model is represented in hierarchical structure consisting of vessel topology (using a parent-child relationship to represent the topological connectivity among a list of a vascular segments), vessel geometry (coordinates and radii), and vessel material property. The 3D model of the vessels is then reconstructed based on the central line geometry. Visual smoothness is achieved by employing operations like sweeping and blending. A variational modeling approach is implemented for vasculature segments. An advantage of such method is that it provides flexibility in changing 3D structure. Where a pathology is identified and measured, a vascular model can be modified to account for the pathology.

Preferably, deformable models are used to detect structures in images. Such models can be used to define a geometry which minimizes the energy of a simulated structure to account for topological change, e.g., due to factors such as blood flow dynamics and even interactions between the device and the body lumen or cavity. For example, catheter tip shape deforms in a predictable manner when straightened with a guide wire, when advancing through tortuous vessels, and when encountering vascular constraints such as lumen narrowing, branch point bifurcations, and the like. These events can be modeled using the simulation system.

In one aspect, a deformation law is applied to a geometric model obtained from a hierarchical central line model to construct a 3D model. This 3D model can be used to model linear deformation, linear forces, non-linear deformation, and non-linear forces. The application of deformation laws to a geometric model is described in, for example, Wang, et al., 1999, *supra*, Mallaldi, et al., *J. Mathematical Imaging and Vision 6(2-3)*: 269-289, 1996; Caselles et al., *Numerische mathematik 66*: 1-31, 1993; Osher and Sethian, *J. Computational Physics 79*: 12-49, 1988; Sethian, In *Level Set Methods*, Cambridge University Press, Cambridge, England, 1996, Caselles et al., *Int. J. Vis. 22(1)*: 61-79; Kichenassamy et al, *Proc. 5th Int. Conf. Computer Vision*, pp. 810-815, 1995).

In a further aspect, the system comprises a knowledge base, relating to the physical and/or biological properties of a patient(s)' body cavity or lumens. Facts within this "vascular material knowledge base" can be derived in part from the geometric modeling arm of the simulation system as well as from public databases (e.g., such as PubMed®) (see, as shown in Figure 1). In one aspect, the property of elasticity can be established from the relationship between image density (determined from a volume image) of a portion of a body cavity or lumen and the stiffness of a particular tissue. In another aspect, the diameter of a cavity/lumen can be determined.

For example, plaque can be distinguished from vessel walls by evaluating the image intensity of a volume image. Preferably, as volume images of body cavities or lumens are acquired from

patients having a disease, data relating to these images are provided to one or more of the knowledge base systems described above. Preferably, the knowledge base system(s) include data from images are obtained from patients having atherosclerosis, coronary vascular lesions, carotid bifurcation stenosis, carotid bifurcation stenosis, abdominal aortic aneurysms, peripheral vascular disease, cerebrovascular disease, cancer, trauma, and congenital malformations that may cause or display vascular manifestations, and the like.

Quantitative measures of a pathology can be obtained. For example, a quantity module which is part of the system can be used to measure the size of a blockage (e.g., a plaque).

In yet another aspect, at least one knowledge base comprises clinical information related to a specific patient for which a device is being designed. This database can include such demographic information as age, sex, drug history, medical history, medical billing information, and the like. This portion of the system can be encrypted so that while information can be continually added to other knowledge bases (e.g., by remote system users), information within the patient-specific knowledge base cannot be tampered with. However, preferably, even information provided by remote system users will be stored in temporary data files until a system operator enables the system to accept the information. Information relating to populations of patients also can be stored for comparison with information relating to the specific patient.

Device Modeling System

Preferably, the first display interface also displays a three-dimensional representation of the medical device which is interfaced with the manikin. A simulation of the device can be obtained from a database of images of stored devices (e.g., where these are known and/or commercially available) or from a simulation of a device, for example, as described in U.S. Provisional Application Serial No. 60/273,734, filed March 6, 2001. A volume scanned image of the device also can be generated using techniques similar to those described above.

Preferably, a physical model is used to simulate a device based on the quantitative analysis of volume-rendered images, followed by a derivation of the geometry, topology, and physical properties of the device. Suitable medical devices which can be simulated include, but are not limited to: a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof. The system is able to model the interactions of multiple devices with each other. For example, the system can model the simultaneous movements of a catheter, guidewire, therapeutic device and the like.

Navigation Modeling System

Preferably, the system simulates the movement of the simulated device within the simulated body cavity or lumen in real-time when a first user manipulates the medical device interfaced with the manikin. This can be realized by performing virtual device navigation inside a simulated body cavity or lumen using an incremental FEM engine. Such a simulation system is described in U.S. Provisional Application 60/273,733, filed March 6, 2001, the entirety of which is incorporated by reference. For example, the embedded FEM engine of the system can provide a real-time simulation of catheter/guide-wire interactions with blood vessels. This enables the first user to develop the eye-hand coordination necessary to implement a particular interventional procedure.

Depending on the realism or deformation accuracy required, the underlying assumption of physical modeling is adapted to simulate navigation and/or deployment of a particular medical device in a body cavity or lumen.

In a preferred aspect of the invention, the system simulates a path which represents at least a portion of a patient's body cavity or lumen and determines fit between the geometry of the device (with or without functional and information attribute layers) and the geometry of the path. The system simulates the design of the device in stages; first providing a simulation based on optimal shape (e.g., using the device shape database), then optimal function, then optimal information parameters.

Basic Models for Catheter Navigation

In a preferred aspect, an incremental Finite Element Method (FEM) is applied to the analysis of catheter navigation. In this basic FEM analysis, blood vessels are assumed to be rigid circular tube-structures with varying radii, or with arbitrary cross-sections and deformabilities. However, it is commonly accepted that because most of the blood vessels within the human body are well stretched by surrounding muscles, the vasculature network is only minimally deformed by catheter navigation. Generally, also the tip of a guidewire or navigating catheter is very soft in order to prevent damage to a blood vessel when in contact. The vessel wall is therefore relatively stiffer than the catheter itself and therefore, it is quite reasonable to simulate a rigid blood vessel wall when simulating navigation and/or deployment of a catheter.

Typical catheters/guidewires are generally cylindrical in shape, with curved or uncurved geometries (e.g., the cross-sections of catheters/guidewires are generally circular or ring-shaped). A

catheter/guidewire can be conceptualized as comprising a plurality of discrete 3D beam elements or segments. Thus, they can be represented as an aggregate of multiple, flexible bodies connected to each other at nodes capable of simulating extension, compression, bending and torsion (i.e., modes of deformation). Thus, catheter navigation can be considered as a sequence of movements of flexible multibody systems comprising a plurality of segments inside the rigid tube-structures (e.g., corresponding to blood vessels).

In one aspect, a simulated catheter is subjected to a simulated force such as pushing, pulling, twisting, or combinations thereof. The movement of the catheter is represented as the sum of rigid-body displacements and deformations at each step with the deformations being relatively small compared to displacements. Generally, the elements of the catheter system are treated as rigid bodies first and then deformations are calculated for individual nodes of elements at their equilibrium position.

A different principle can be employed which is based on a virtual work method or multibody dynamics method (MDM). The MDM models the kinematics (rigid body displacements) of a multibody system. In contrast, the FEM models the deformations of flexible bodies to analyze catheter navigation. Generally, the deformation of a medical device such as a catheter is relatively small relative to the rigidity of a lumen, such as a blood vessel and Hooke's law is applied. However, where the deformation of a lumen is large (for example, when biomaterials fail), nonlinear FEM should be applied.

The Governing Equation

Consider a catheter represented by multiple, discrete elements, each with a deformed configuration. This flexible multibody system is in dynamic equilibrium with applied forces (e.g., contact traction and internal forces) at time t. An example of an internal force is a hyper-viscoelastic force in an isotropic constitution model (see, e.g., *The Biomedical Engineering Handbook*, Editor-In Chief, Joseph D. Bronzino, CRC Press + IEEE Press, 1995).

Two coordinate systems can be used to describe the movement and the deformations of the catheter system. The coordinate system XYZ is the inertial (global) reference frame and xyz is the body (local) reference frame at time t.

The variational equations of motion of the catheter system are given as

$$\int_S \delta\bar{u}^T \bar{T} dS - \int_V \delta\bar{u}^T (\rho\ddot{\bar{u}} - \bar{f}) dV = \int_V \delta\bar{\varepsilon} (\bar{\sigma} - \bar{\sigma}^0) dV \quad (1)$$

where
S denotes the boundary surface,
V denotes the volume of the catheter,
$\bar{u}$ denotes the displacement vector of a catheter point at time t,
$\bar{\varepsilon}$ and $\bar{\sigma}$ denote the strain vector and stress vector, respectively,
$\bar{\sigma}^0$ denotes the residual stress vector due to the accumulation of the previous deformations which can be reduced through a process of energy release (shape recover),
$\delta\bar{u}$ denotes the virtual displacement vector that is consistent with the constrain conditions,
$\delta\bar{\varepsilon}$ denotes the corresponding virtual strain vector,
ρ denotes the mass density of the catheter,
$\bar{f}$ denotes the body force vector,
$\ddot{\bar{u}}$ denotes the acceleration vector (second order differentiation of variables with respect to time t), and
T is the traction vector and can be expressed in terms of the external force applied at the boundary S and the contact force between the catheter and the walls of the vessels.

The displacement vector can be defined as a summation of two terms, a term representing rigid body displacement and a deformation term, in order to derive an explicit equation which can be solved to simulate catheter movement. Because rigid displacement of the catheter results in no strain or stress, the final two variational equations from (1) can be formulated as

$$\int_S \delta\bar{u}_r^T (\bar{T}_a + \bar{T}_c) dS - \int_V \delta\bar{u}_r^T (\rho\ddot{\bar{u}}_r - \bar{f}) dV = 0, \quad (2)$$

representing the movement of catheter/multibody system, with each element moving as a rigid object and

$$\int_S \delta\bar{u}_f^T (\bar{T}_a + \bar{T}_c) dS - \int_V \delta\bar{u}_f^T (\rho\ddot{\bar{u}}_r - \bar{f}) dV = \int_V \delta\bar{\varepsilon}_f (\bar{\sigma}_f - \bar{\sigma}^0) dV \quad (3)$$

where $\bar{u}_r$, denotes the rigid displacement; $\bar{u}_f$ represents the deformation, $\bar{T}_a$ and $\bar{T}_c$ represent the external force and contact force, respectively; and $\bar{\varepsilon}_f$ and $\bar{\sigma}_f$ represent the strain and stress corresponding to the deformation. It is assumed here that deformations are generally smaller than the rigid displacements. The deformation can then be assumed to be time independent during navigation. Because of this, the acceleration of deformation is not taken into consideration in this formula.

FEM Analysis

Three-dimensional (3D) beam elements can be used to derive equations for FEM analysis of catheter movement. Equations (2) and (3), above, can be rewritten for a catheter with N elements, where

$$\sum_{n=1}^{N}\int_{S_n}\delta\bar{u}_r^T(\bar{T}_a+\bar{T}_c)dS-\sum_{n=1}^{N}\int_{V_n}\delta\bar{u}_r^T(\rho\ddot{\bar{u}}_r-\bar{f})dV=0 \tag{4}$$

represents the rigid body displacement of the beam elements and

$$\sum_{n=1}^{N}\int_{S_n}\delta\bar{u}_f^T(\bar{T}_a+\bar{T}_c)dS-\sum_{n=1}^{N}\int_{V_n}\delta\bar{u}_f^T(\rho\ddot{\bar{u}}_r-\bar{f})dV=\sum_{n=1}^{N}\int_{V_n}\delta\bar{\varepsilon}_f^T(\bar{\sigma}_f-\bar{\sigma}^0)dV \tag{5}$$

represents the deformations of the elements. S_n and V_n denote the boundary and volume of the nth element, respectively.

Equations (4) and (5) can be solved using routine FEM methods to derive the matrix equations:

$$\bar{M}\ddot{\bar{U}}=\bar{T}_a+\bar{T}_c+\bar{f} \tag{6}$$

$$\bar{K}\bar{u}=\bar{T}_a+\bar{T}_c-\bar{M}\ddot{\bar{U}}+\bar{f}+\bar{\delta}^0 \tag{7}$$

providing a multidynamic analysis of rigid body displacements and for an FEM analysis of deformations for a simulated catheter. The rigid body displacement vector $\bar{u}$ is represented by three translations and three rotations at each FEM node, while the deformation vector $\bar{U}$ is also expressed in the same way, with a total of six degrees of freedom at an FEM node. Matrices $\bar{M}$ and $\bar{K}$ denote the global mass matrix and the global stiffness matrix, respectively. Note that equations (6) and (7) are coupled to each other and can be solved using a semi-implicit iteration method (see, e.g., Rao, In *The Finite Element Method in Engineering*, 2nd Edition, New York: Pergamon Press, 1989).

Advanced Models

In one aspect, vessels are not treated as rigid cylindrical structures but as deformable structures. This is particularly useful when modeling the interaction of catheterization devices, such as balloon and stents, with diseased arteries. These vessels vary in cross-sectional diameter due to the presence of a pathology, such as stenosis. Further, the deformation properties of diseased vessels are different from the deformation properties of normal vessels. Additionally, it may be desirable to model one or more physiological parameters such as the effect of blood flow on navigation of a medical device such as a catheter. Therefore, in one aspect, the simulation process uses a hemodynamic model describing the blood flow phenomenon. Preferably, the hemodynamic model accounts for the affects of such variables, as disease, age, obesity, and the like.

For a more realistic and accurate analysis of the interaction between a device and a pathology such as coronary stenosis, the device materials and vessels are treated as nonlinear. Blood flowing through the vessels is modeled by treating the blood as a homogeneous incompressible Newtonian fluid. The vessels and associated stenosis are modeled as layered structures, using a 3D space FEM model. Physiological influences on a body cavity or lumen also can be considered in particular anatomic locations in which these influences may be important concerns. For example, when modeling coil deployment in the head, the system can take blood flow dynamics into account, since a coil may be swept away if incorrectly placed.

Preferably, FEM analysis occurs in real-time, in order to simulate real-time movement of a representation of a device while a user is manipulating a model device in the manikin. Such training is important to developing eye-hand coordination. Preferably, this is implemented using a fully nonlinear 3D finite element model combined with hemodynamic analysis. This requires extensive computer power. A multiprocessor system with at least about four processors, with each processor having computing power equal to a 2 GHz Intel Pentium 4 CPU is one example of a system that might be used.

Preferably, the system models interactions between the physiology and anatomy of a patient and one or more medical devices using physical modeling. Figure 16 is a block diagram illustrating the various steps in such a simulation process and how these interact with each other. Preferably, the system accounts for physiological responses to an intervention procedure. For example, in simulating damage to a vessel wall through excessive pushing of a device against the wall, the system also can simulate the effect such an action will have on blood pressure. Similarly, a simulation of a tumorous lesion in a blood vessel include modeling the effects of such a lesion on local mechanical properties of tissues.

In a preferred aspect, the system includes a patient database comprising stored volume images and files relating to optical data obtained from body cavities and lumens of one or more patients. Preferably, the database comprises data from a population of patients, such as a population of normal patients, a population of patients with coronary artery disease, peripheral vascular disease, stenosis, and the like. In one aspect, the database comprises vascular data from patients obtained through one or more of a 3D Rotational XR scanner, an MRI scanner, an MRA scanner, or any scanning device suitable for collecting scanned images for generating volume images. Data so obtained generally is segmented. By having two rounds of scanning using the same scanning, but with only one round revealing the vasculature, segmented vessels can be obtained by subtracting images of the former scan from the corresponding images in the latter scan.

Figure 15 illustrates the creation of a physical model for a patient's vasculature. Based upon segmented volume images, nodes are extracted, along with position and contour information. This data defines the central line of a vessel. Preferably, nodes are labeled according to the direction of blood flow as this aids in the deformation analysis process. After a 3D geometric model is reconstructed from the medical images, using the geometric modeling system as described above, a deformation law is implemented using FEM.

Deployment Models

In one aspect, in addition to modeling movement of a device through a body cavity or lumen, the system models one or more operations of the device. Such operations include, but are not limited to: a surgical procedure (e.g., such as removing, cutting, or repairing a tissue), inflation or deflation of a balloon, injection of a radioopaque material into the body cavity or lumen, and the like.

In one aspect, the system models interactions between an angioplasty device and a blood vessel having one or more lesions. For example, the system can model the deployment of a balloon angioplasty device at a lesion site and can model inflation and deflation of the balloon at the site. Preferably, a visual simulation is implemented at the same time that a user manipulates a balloon-inflating device. In one aspect, the balloon-inflating device comprises a delivery mechanism for controlling delivery of fluid (e.g., such as air) to a balloon, a pressure sensor for monitoring pressure of a fluid delivered to the balloon, and an electrical pressure meter for reading pressure determined by the pressure sensor. The electrical pressure meter transmits a signal corresponding to a pressure value to the system processor and, in response, the system simulates deployment of the balloon both on the screen of the first user device and within the manikin.

Injection of contrast medium also can be simulated. In one aspect, the first user (or a second user training the first user) can select an injection volume and rate from selectable options displayed on the first user interface (or second user interface). When these injection parameters are set, injection can be triggered using a simulated syringe or button on the control panel. The appearance of contrast filling the vessels (opacity) is modeled to reflect the rate of injection relative to the blood flow rate in the vessel. This provides a realistic impression of the injection. Preferably, diastolic and systolic flow pattern and washout of contrast through the vasculature also are modeled using the contrast injection function. Roadmapping capabilities additionally can be made available. The value of roadmapping is enhanced when it is combined with simultaneous 3D display of the vasculature.

Simulation Methods

In one aspect, the system provides a haptic interface for providing an interventional radiologist with the sense of touch during pretreatment planning and training. The system can be used in preparation for catheterization procedures with cerebral vascular pathologies such as intracranial aneurisms, stenosis, arteriovenous malformations, and the like. Other simulations which can be performed using the system include, but are not limited to, angioplasty, catheter navigation in the abdominal aorta, peripheral intravenous catheterization, venipuncture, interventional cardiology, and the like.

Figure 13 is a flow diagram illustrating a simulation according to one aspect of the invention. Preferably, the simulation is event driven, i.e., responding to discrete actions from one or more users. Computation of interactions between the body cavity or lumen and one or more medical devices is implemented by the FEM engine described above. FEM has been used widely to compute deformations under mechanical constraints in engineering; however, the instant invention applies FEM analysis to various physical models of blood vessels, blood flow dynamics and medical devices.

Any input from users comes in the form of device manipulations, such as pushing, pulling, twisting a catheter; deploying a coil; inflating a balloon with a balloon catheter. Each of these inputs affects the finite element structure modeled by the system. By solving equations representing this structure through an iterative process as described above, an equilibrium state representing the interaction between the device and cavity/lumen can be obtained. At the equilibrium state, the interacting devices and vessels are at their final deformable forms. The forces computed at each node of the interaction between a medical device/body cavity or lumen are then fed back to one or more users using simulated instruments interfacing with the system. System outputs include real-time representations of medical devices as they navigate and/or deploy in simulated body cavities or lumens.

Real-time interaction is an important feature of the instant invention. The immersion of a user, and therefore, his or her ability to learn from the simulation system, is directly linked to the bandwidth of various components of the simulation system. An acceptable bandwidth for visual display is in the range of about 20-60 Hz while an acceptable bandwidth for haptic display is in the range of about 300-1000 Hz (where 300 Hz is the free hand gesture frequency).

Two parameters that are particularly important for accurate perception by a user are latency and computation time. Latency measures the time between sensor acquisition (e.g., acquiring the position of a simulated medical device relative to a simulated body cavity/lumen) and system action (e.g., haptic rendering or force feedback). Computation time is that amount of time needed to

determine the equilibrium state of a structure (e.g., a representation of a device and cavity/lumen) and to update the resulting models.

There are several contributing causes of latency, including, but not limited to: time required for communication between input devices and the system processor, time for communication between the haptic display and the system processor, time for communication between the visual display (e.g., the 2D display) and the processor, time to compute collision detection, time for force feedback, and time for computing deformation models. Latency depends greatly on hardware and preferably the system comprises an at least about 16-bits bus for internal transmission within the embedded system (e.g., manikin interface), and a combination of serial and USB transmissions to create external links between simulated devices and the system processor.

Realism is also important. Very often, real-time interaction and realism are correlated. For example, Figure 14 shows the relationship between response time and realism. Preferably, the simulation system according to the invention provides a visual feedback of 12-15 frames per second.

Visual feedback is the most powerful perception channel. The quality of visual rendering greatly influences user immersion and therefore the effectiveness of the simulation system. The system provides a library of 3D representations of medical devices and a library of 3D representations of normal or pathological patient anatomy. In one aspect, the user can select an entry point for insertion of a medical device into a simulated patient (e.g., at either a radial or femoral site) and in response to the user's manipulation, a haptic display will display the navigation of the device through a selected body cavity or lumen. The system can be used to direct the navigation of the device towards or away from the heart, allowing a user to choose where navigation will begin to be tracked. The user interface can comprise direction buttons, enabling a user to maneuver the device in particular directions.

Preferably, a current position of a navigating catheter within a body cavity/lumen is overlaid on a fluoroscopic view. When required, especially, during a course of training, a user has the option to adjust a fluoroscopic image in a manner similar to that employed in a CathLab. For example, the user can zoom in/out of a particular view of a catheter-guidewire entry site for a closer look of the position and orientation of the catheter and guidewire. The user also can improve image quality by collimating the field of view using the shutter function of a simulated scanning device. The shutter function provides both lateral and vertical collimation to recreate a clinical setting. The contrast of the fluoroscopic image also can be modified. In addition, moving patient table control levers can change the position of the fluoroscopic field of view. These levers control the movement of the

image in the X and Y-axes as well as rotation and skew. They correspond to patient table control levers used in the clinical setting.

As discussed above, the motion of one or more medical devices relative to a body cavity or lumen is tracked and updated simultaneously in fluoroscopic and 3D displays. The user can change the transparency of 3D rendered vessels to better compliment the geometry presented in the fluoroscopic view. The user also has the option of overlapping a representation of the device with a representation of a surface-rendered vasculature. 3D-rendered vessels can be rotated in the x-, y-, and z-axis to better appreciate the position of the catheter/guidewire tip relative to the vascular anatomy. This feature is very useful in teaching selective vessel catheterization techniques. Besides 3D views, a fluoroscopic image can be viewed in stereo mode with the stereo image projected onto a split screen alongside the 2D image of a vessel. Users see the stereo virtual image on the screen of their user devices wearing a pair of stereo glasses (e.g., such as StereoGraphic Crystal Eyes). The stereo virtual objects consist of vessels, associated volume data, and the one or more interventional devices being navigated and/or deployed through the vessels.

Besides providing stereo and 3D views of the catheterization process, the simulator has the capability of locating catheter tip position within multi-planar images of a body region. The system will highlight tip position relative to anatomical structures on the display of one or more user devices. Preferably, images of the tip are viewable in any of an axial, coronal, sagittal or combined mode, representing images of scanned anatomical structures (e.g., such as obtained from CT, MRI or actual cross-anatomical color images). It is an important aspect of the system to provide multi-functional views for teaching complex techniques, such as those used in interventional procedures. In one aspect, an endoscopic view is provided of the tip of the catheter within the enclosing vessels of the cardiovascular system.

In another aspect, the system provides a haptic system for providing a neuroradiologist with the sense of touch during pretreatment planning and training. Preferably, the system comprises a database of angiographic information and a vascular model can be extracted from a database comprising data relating to geometry and topology of the cerebral vasculature (e.g., using a knowledge base). Physical properties of vessels can be obtained from outside sources such as the literature or from various experts. A library of devices suitable for use with vessels in the brain is included in the system. In one aspect, the library comprises data files relating to the geometry and/or physical properties of interventional devices, such as catheters, guidewires, stents, and coils. A device shape and material knowledge base can be provided as described in U.S. Provisional Application Serial No. 60/273,734, filed March 6, 2001.

In one aspect, the system simulates an intracranial blood vessel with an aneurysm. Intracranial aneurysms are berry-like blisters in cerebral arteries that are caused by a weakness of all vessel wall layers. If rupture of an aneurysm occurs, hemorrhage can cause serious damage to the brain. To prepare for an interventional proceeding, a clear understanding of the anatomy surrounding an aneurysm is critical, such as the location and size of the neck, or connection between the aneurysm and vessel which feeds into it. An aneurysm is usually clearly visible in volume and surface-rendered images.

Preferably, the system displays a representation of the aneurysm and surrounding blood vessels and models the interactions of a simulated device being maneuvered in proximity to the aneurysm. In one aspect, the system is used to simulated the placement of one or more coils to treat the aneurysm. In one aspect, aneurysm coiling is simulated by navigating a medical device such as a coilwire to the aneurysm and replacing the wire with a coil. The coil is deployed by detaching the coil from the wire. Multiple coils can be deployed by repeating the detachment process with new coil wires. Each of these actions can be simulated on the haptic display using the system according to the invention.

In other aspect, a user can simulate other interventional procedures such as contrast fluid injection, inflation or deflation of a balloon, stent deployment, injection of a drug or therapeutic agent. The system provides both haptic and visual feedback to the user to enable the user to develop the eye-hand coordination necessary to become skilled in these procedures.

As described above, the invention produces a highly realistic simulation environment for preplanning image-guided medical device delivery procedures and for training individuals who perform such procedures. In addition to its application in biomedical engineering, component parts of this invention may be applied to many other fields, for example, such as the field of 3D computer games. It should be apparent to those of ordinary skill in the art that variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and scope of the invention and the claims.

All of the references, patents, and applications identified above, are expressly incorporated herein in their entireties.

What is claimed is:

1. A system for simulating movement of a medical device in a body cavity or lumen of a patient, comprising:

   (a) a medical device comprising a first end for manipulation by a user and a portion comprising a second end insertable into a simulated body cavity or body lumen in a manikin;

   (b) a manikin comprising an interface for receiving the portion comprising the second end and for interfacing with a simulated body cavity or lumen within the manikin, wherein the interface comprises a directional force feedback mechanism for exerting a directional force on the medical device in response to a feedback signal received by the force feedback mechanism.

2. The system according to claim 1, wherein the directional force feedback mechanism provides resistance to forward motion but enables free reverse motion in response to the feedback signal.

3. The system according to claim 1, wherein the directional force feedback mechanism comprises a rolling element coupled to the portion of the device comprising the second end and wherein an internal surface of the simulated cavity or lumen in the manikin comprises an oblique slot for receiving the rolling element.

4. The system according to claim 3, wherein, in response to a feedback signal, forward movement of the second end causes the rolling element to be received by the slot, thereby causing resistance to further forward motion.

5. The system according to claim 4, wherein a motor controls movement of the rolling element.

6. The system according to claim 1, further comprising a tactile feedback mechanism.

7. The system according to claim 6, wherein the tactile feedback mechanism provides continuous vibrational feedback to a user holding the medical device.

8. The system according to claim 8, wherein continuous vibrational feedback is provided through a continuously rotating motor in communication with the portion of the device comprising the second end.

9. The system according to claim 1, wherein a position of at least the second end of the medical device relative to the manikin is continuously tracked.

10. The system according to claim 9, wherein the medical device comprises an encoder for tracking the translation of the device and an encoder for tracking the rotation of the device.

11. The system according to claim 9, wherein the system further comprises a tracking unit comprising a light source, a signal processing circuit, and one or more optical sensors, wherein the tracking unit is placed within the interface in optical communication with the device when it is inserted into the cavity or lumen.

12. The system according to claim 11, wherein light from the light source reflects on the device when inserted and wherein the reflected light is received by the one or more optical sensors.

13. The system according to claim 12, wherein changes in reflected light received by the one or more sensors is detected by the system, and wherein, in response to this detection, the system simulates movement of the device in real-time on the user display.

14. The system according to claim 12, wherein two optical sensors are provided which are perpendicular to one another.

15. The system according to claim 12, wherein the tracking unit is configured in the form of a rail along which the device can move.

16. The system according to claim 10, wherein one or more additional medical devices comprising a first end for manipulation by a user and a portion comprising a second end for insertion into the simulated body cavity or body lumen, are inserted into the interface and wherein the position of each medical device is independently monitored.

17. The system according to claim 16, wherein the one or more medical devices are selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof.

18. The system according to claim 1, further comprising a table for placing the manikin thereon, wherein the table comprises a processor connectable to the network.

19. The system according to claim 18, wherein the system further comprises at least one first user device connectable to the network, the first user device comprising a first display interface for displaying a three-dimensional representation of a simulated body cavity or lumen of a patient.

20. The system according to claim 19, wherein the first display interface further displays a three-dimensional representation of a medical device corresponding to a medical device which is interfaced with the manikin and wherein the system simulates on the display the movement of the medical device within the simulated body cavity or lumen of the manikin in real-time when a first user manipulates the medical device interfaced with the manikin.

20. The system according to claim 19, further comprising a simulated scanning display for displaying a two-dimensional image of the simulated body cavity or lumen.

21. The system according to claim 20, wherein the simulated scanning display is part of a simulated scanning device.

22. The system according to claim 21, wherein the simulated scanning device is simulating an x-ray imaging system.

23. The system according to claim 21, wherein the simulated scanning device and scanning display are coupled to a movable C-arm within scanning distance of the manikin.

24. The system according to claim 1, further comprising a re-configurable control panel for performing one or more of: image acquisition selection; image display; manipulating a table on which the manikin is placed; manipulating the position of a simulated scanning device relative to the manikin; and control of one or more shutter devices for limiting a field of view of a scanning device placed within scanning distance of the manikin.

25. The system according to claim 1 or 20, further comprising a monitoring station, the monitoring station comprising a second user device connectable to the network and comprising a second display interface for enabling a second user to monitor the movement of the medical device within the simulated body cavity or lumen.

26. The system according to claim 25, wherein the second display interface of the monitoring station displays selectable options enabling the second user to select or change one or more anatomical and/or physiological parameters of the simulated body cavity or lumen, and wherein the selection causes the three-dimensional image of the simulated body cavity or lumen displayed to the first user to change to reflect the changed anatomical and/or physiological parameters.

27. The system according to claim 20, wherein the system is connectable to a database of patient images and/or medical data.

28. The system according to claim 25, wherein the system is connectable to a database of patient images and/or medical data.

29. The system according to claim 27, wherein the patient images comprise images of a body cavity or lumen from a patient affected by a pathology.

30. The system according to claim 28, wherein the patient images comprise images of a body cavity or lumen from a patient affected by a pathology.

31. The system according to claim 21, further comprising at least one foot-activation switch for activating or collimating the simulated scanning device, image display or table movement

32. The system of claim 1, wherein said lumen is a blood vessel.

33. The system according to claim 27, wherein the first user display interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the first user display interface.

34. The system according to claim 27, wherein the second user display interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the second user display interface.

35. The system according to claim 33, wherein the second user display interface provides access to the database and wherein, in response to accessing, the system displays an image and/or medical data on the second user display interface.

36. The system according to claim 35, wherein the second user display interface provides a selectable option enabling a second user to display the image displayed on the second user display interface, on the first user's display interface.

37. The system according to claim 1, wherein the device is selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof.

38. A syringe for simulating fluid delivery, comprising:

a housing defining a lumen comprising an opening for delivering a fluid;

a pushing element for pushing the fluid through the opening;

a friction-producing element in communication with the pushing element; and

a motor in communication with the friction-producing element and comprising a signal-receiving element,

wherein the friction-producing element causes friction between the pushing element and a surface of the lumen of the housing upon activation by the motor in response to a signal received by the signal-receiving element.

39. The syringe according to claim 38, wherein the motor, when activated, causes motion of the friction-producing element, thereby causing the friction-producing element to contact the surface of the lumen of the housing, creating friction between the pushing element and the surface of the lumen and resistance to the motion of the pushing element.

40. The syringe according to claim 38, wherein the friction-producing element comprises one or more rubber pads.

41. The syringe according to claim 40, wherein each rubber pad is coupled to an arm whose movement is controlled by the motor.

42. The syringe according to claim 41, wherein each arm is coupled to the motor through a gear attached to the motor.

43. The syringe according to claim 38, wherein the amount of friction produced by the friction-producing element is adjusted by controlling a rotation angle of the motor.

44. The system according to claim 1, further comprising the syringe of claim 38, wherein opening of the syringe is connectable to a connecting piece having a first end for receiving fluid from the opening and a second end for delivering fluid to a simulated body cavity or body lumen in the manikin.

45. A balloon-inflating device for simulating deployment of a balloon within a body cavity or lumen of a patient, comprising:

a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon;

a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device;

an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor.

46. The system according to claim 1, further comprising the balloon-inflating device of claim 45.

47. The system according to claim 20, wherein the system simulates deformation of the body cavity or lumen by the medical device.

48. The system according to claim 20, wherein the system simulates an operation of a medical device selected from the group consisting of: a surgical procedure, inflation or deflation of a balloon, injection of a radioopaque material into the body cavity or lumen, and combinations thereof.

49. The system according to claim 20, wherein the system simulates the movement of the device within a blood vessel.

50. The system according to claim 49, wherein the blood vessel is in the brain.

51. The system according to claim 50, wherein the blood vessel is in the heart.

52. A method for simulating the movement of a medical device in the body cavity or lumen of a patient, comprising:

providing a medical device comprising a first end for manipulation by a user and a portion comprising a second end inserted into a simulated body cavity or body lumen in a manikin, wherein the simulated body cavity or lumen in the manikin comprises a directional force feedback mechanism, and

wherein, in response to a feedback signal, the directional force feedback mechanism creates resistance to forward motion of the medical device but allows free reverse motion.

53. The method according to claim 52, further comprising:

providing a system comprising:

a processor in communication with the directional force feedback mechanism, the processor connectable to the network; and

a first user device in communication with the processor, the first user device comprising a first display interface for displaying a representation of a body cavity or lumen; and for providing access to a database of three-dimensional images of body cavities and lumens from a plurality of different patients; and

enabling a user to select from the database a representation, wherein in response to the selection, the representation is displayed on the first display interface.

54. The method according to claim 52, wherein the first display interface a displays a three-dimensional representation of the medical device and wherein the system simulates the movement of the medical device within the body cavity or lumen in real-time as a first user manipulates the medical device which is interfaced with the manikin.

55. The method according to claim 52 or 53, further comprising providing a monitoring station comprising a second display interface in communication with the processor and the first display interface, and wherein the second display interface provides a second user with access to the database.

56. The method according to claim 54, wherein when a second user selects a representation from the database, the representation is displayed on both the first and second display interface.

57. The method according to claim 53, wherein the system simulates the deformation of a body cavity or lumen in response to movement of the medical device by the first user and displays the representation of the deformation on the first display interface.

58. The method according to claim 53, wherein the medical device performs an operation on the simulated body cavity or lumen and the first display interface displays a simulation of the operation.

59. The method according to claim 58, wherein the operation is inflation or deflation of a balloon within the simulated body cavity or lumen.

60. The method according to claim 58, wherein the operation is injection of a radioopaque fluid within the body cavity or lumen.

61. The method according to claim 52, wherein the device is selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, an optical probe, a drug delivery device, and combinations thereof.

62. The method according to claim 54, wherein a first user inserts one or more additional medical devices into the simulated body cavity or lumen, and the movement of each medical device is independently monitored.

63. The method according to claim 52, wherein the simulated body cavity or lumen in the manikin further comprises a tactile feedback mechanism, providing continuous vibrational feedback to a first user manipulating the device.

64. A method for simulating fluid delivery into a body cavity or lumen of a patient comprising:

(a) providing a syringe for simulating fluid delivery, the syringe comprising:

a housing defining a lumen comprising an opening for delivering a fluid;

a pushing element for pushing the fluid through the opening;

a friction-producing element in communication with the pushing element; and

a motor in communication with the friction-producing element and comprising a signal-receiving element,

wherein the friction-producing element causes friction between the pushing element and a surface of the lumen in response to a signal received by the signal receiving element; and

(b) providing a signal, thereby causing friction between the pushing element and the lumen.

65. A method for simulating deployment of a balloon within a body cavity or lumen of a patient, comprising:

(a) providing a balloon-inflating device, comprising:

a delivery mechanism for controlling delivery of a fluid through the balloon-inflating device to the balloon;

a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device;

an electrical pressure meter for reading pressure determined by the pressure sensor and for transmitting a signal corresponding to a pressure value to a processor;

(b) providing a system comprising:

a processor for receiving the signal, the processor connectable to the network; and

a user device comprising an interface displaying a representation of the balloon within a simulated body cavity or lumen; and

(c) delivering the fluid to the balloon; wherein deployment of the balloon in response to the delivering is displayed on the user device.

66. The method according to claim 65, wherein the fluid is air.

67. The method according to claim 65, wherein the method is used to simulate balloon angioplasty.

68. The method according to claim 65, further comprising providing the system according to claim 1, inserting a balloon catheter into the simulated body cavity or lumen to simulate navigating to a target region of the body, and simulating positioning the balloon deployment device in proximity to the balloon catheter to inflate or deflate the balloon.

69. The method according to claim 67, further comprising inserting a catheter and guidewire into the body cavity or lumen to navigate the balloon cavity to the target region.

70. The method according to claim 67, further comprising inserting a stent catheter to navigate to a target region and using the balloon to deploy the stent, thereby simulating stent deployment in the body cavity or lumen.

71. The method according to claim 68, further comprising inserting a catheter or guidewire into the body cavity or lumen to navigate the stent catheter to the target region.

72. A method for simulating coil embolization in a body cavity or lumen of a patient, comprising:

providing a catheter, guidewire and coil wire comprising a coil to navigate to a target region of the body;

providing the system according to claim 19, wherein the re-configurable control panel provides a selectable option for detaching the coil from the coil wire, and wherein selecting the selectable option triggers the release of the coil from the coil wire.

73. The method according to claim 72, wherein an electrical current triggers release of the coil from the coil wire.

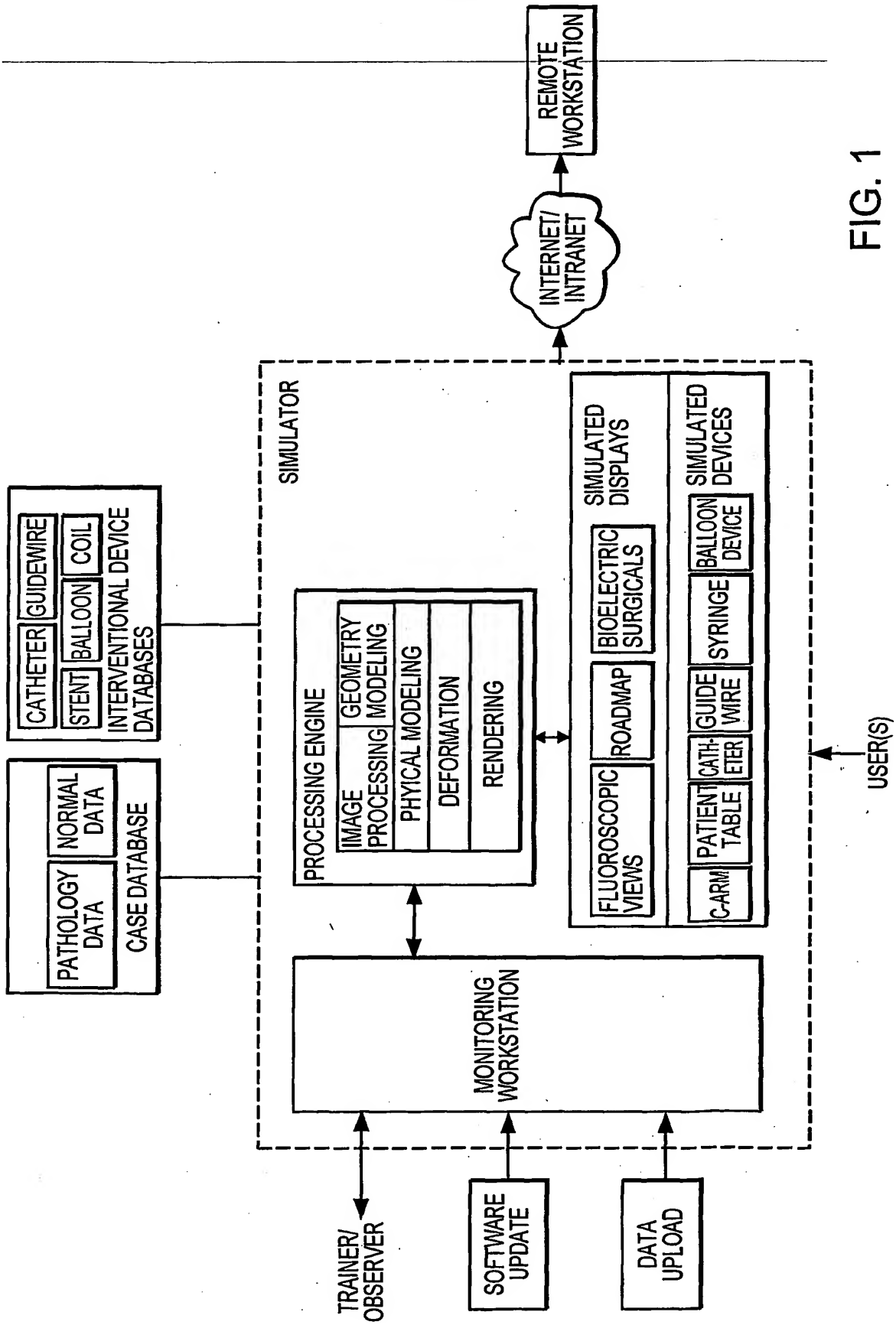

REMOTE WORKSTATION
INTERNET/ INTRANET
SIMULATOR
CATHETER
GUIDEWIRE
STENT
BALLOON
COIL
INTERVENTIONAL DEVICE DATABASES
PATHOLOGY DATA
NORMAL DATA
CASE DATABASE
PROCESSING ENGINE
IMAGE PROCESSING
GEOMETRY MODELING
PHYICAL MODELING
DEFORMATION
RENDERING
SIMULATED DISPLAYS
FLUOROSCOPIC VIEWS
ROADMAP
BIOELECTRIC SURGICALS
SIMULATED DEVICES
C-ARM
PATIENT TABLE
CATH-ETER
GUIDE WIRE
SYRINGE
BALLOON DEVICE
USER(S)
MONITORING WORKSTATION
TRAINER/ OBSERVER
SOFTWARE UPDATE
DATA UPLOAD

FIG. 1

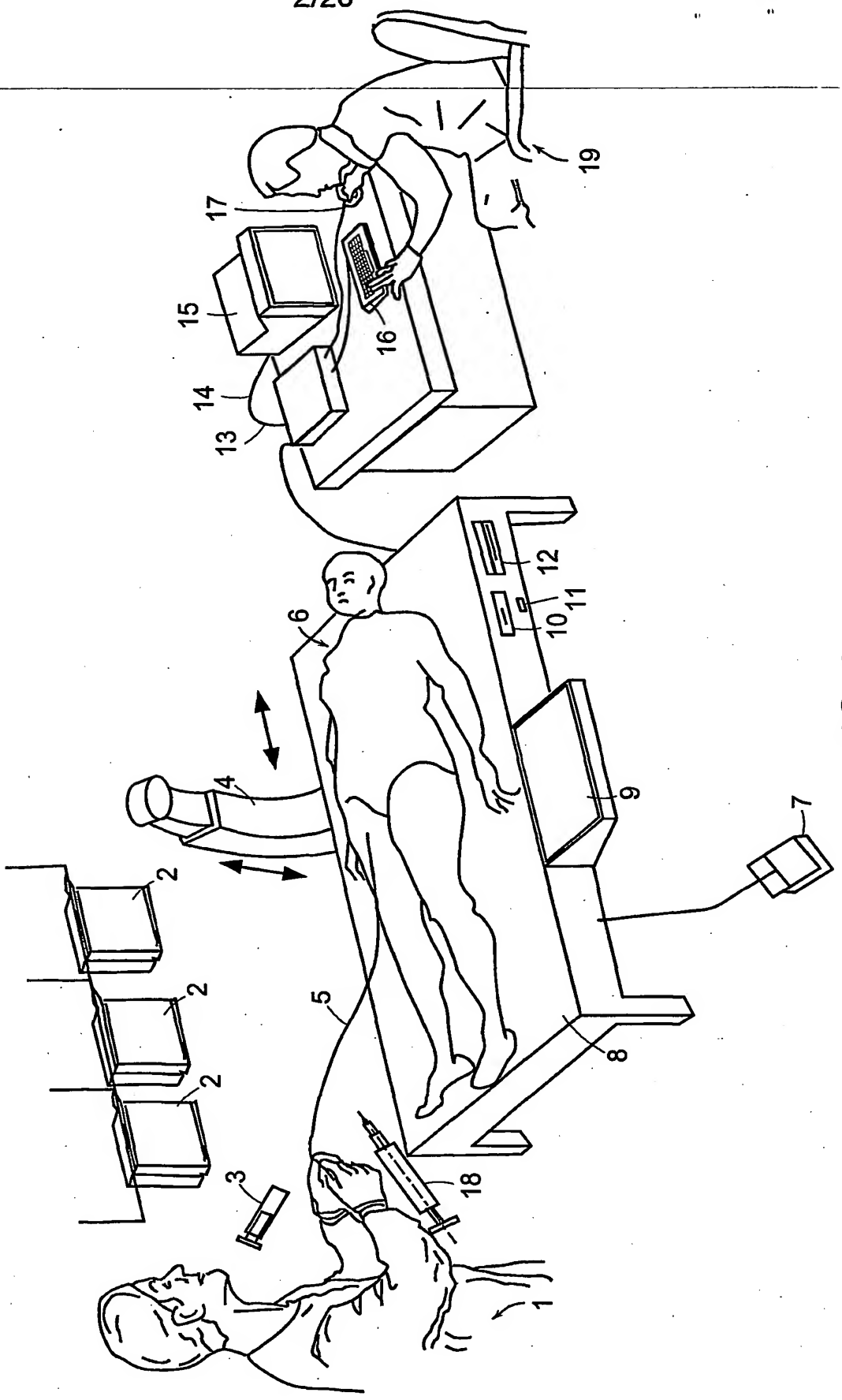


FIG. 2

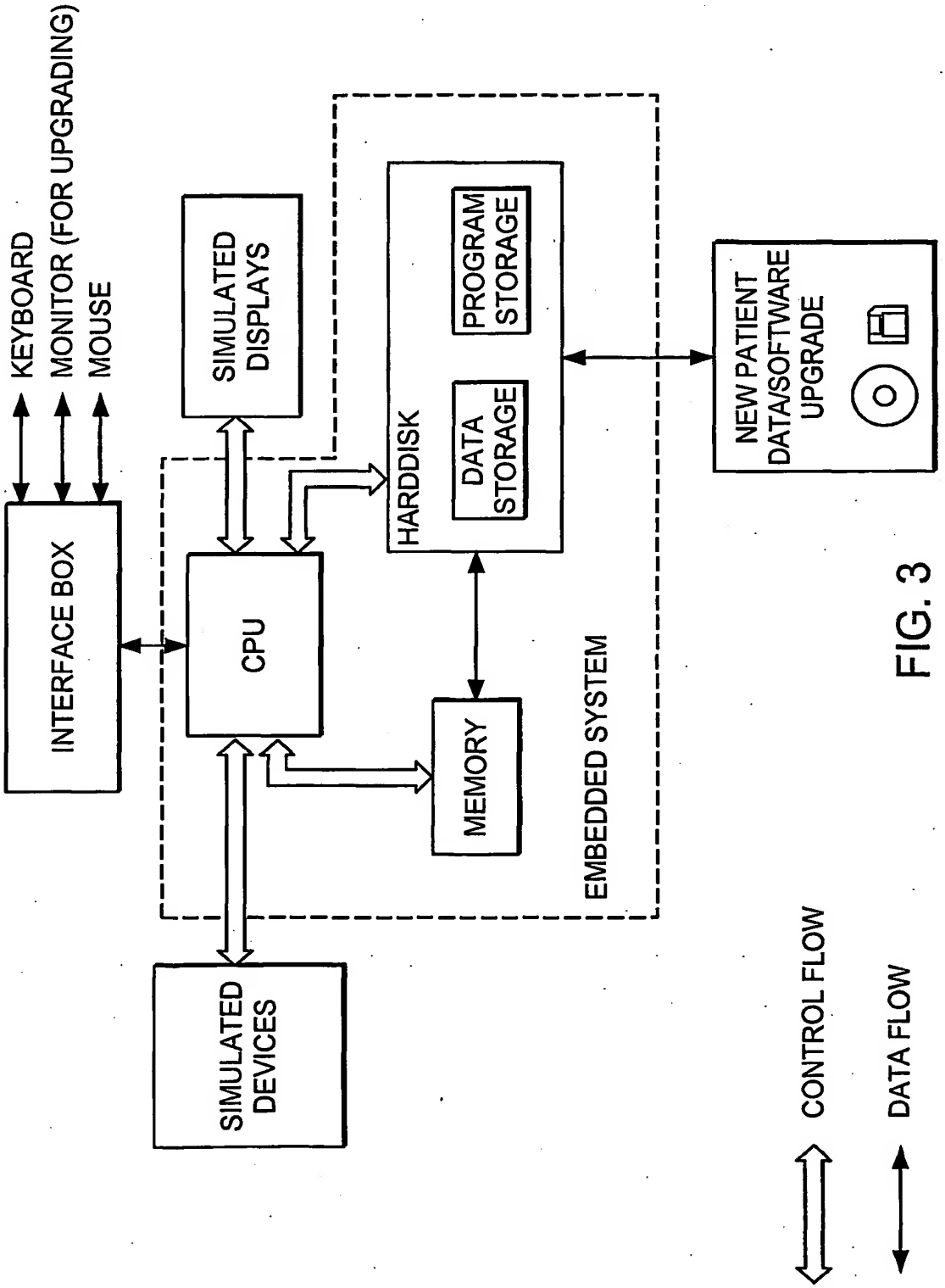
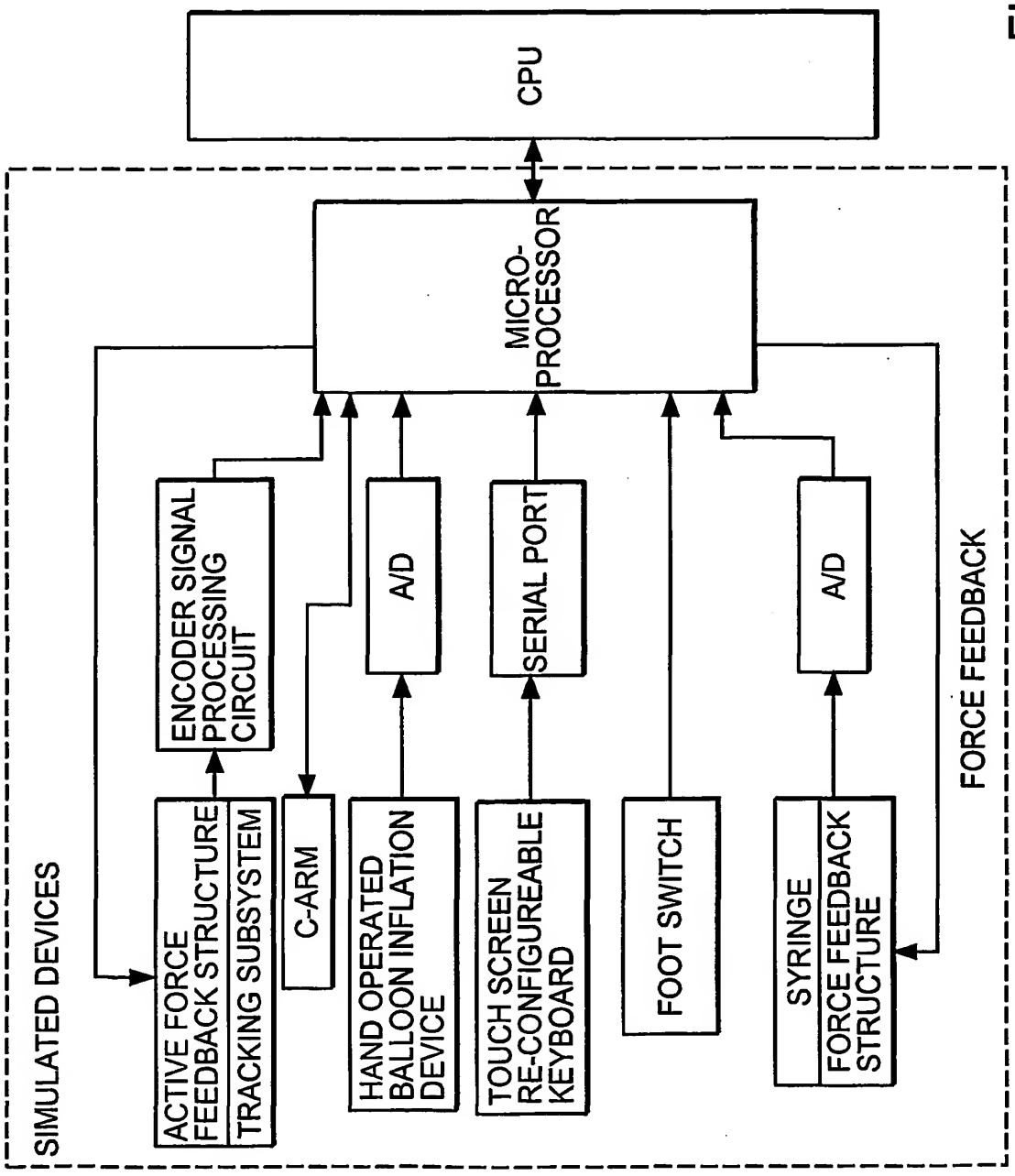

KEYBOARD
MONITOR (FOR UPGRADING)
MOUSE
INTERFACE BOX
SIMULATED DISPLAYS
CPU
HARDDISK
PROGRAM STORAGE
DATA STORAGE
MEMORY
EMBEDDED SYSTEM
NEW PATIENT DATA/SOFTWARE UPGRADE
SIMULATED DEVICES
CONTROL FLOW
DATA FLOW

FIG. 3

FIG. 4


CPU
MICRO-PROCESSOR
SIMULATED DEVICES
ENCODER SIGNAL PROCESSING CIRCUIT
A/D
SERIAL PORT
A/D
FORCE FEEDBACK
ACTIVE FORCE FEEDBACK STRUCTURE
TRACKING SUBSYSTEM
C-ARM
HAND OPERATED BALLOON INFLATION DEVICE
TOUCH SCREEN RE-CONFIGUREABLE KEYBOARD
FOOT SWITCH
SYRINGE
FORCE FEEDBACK STRUCTURE

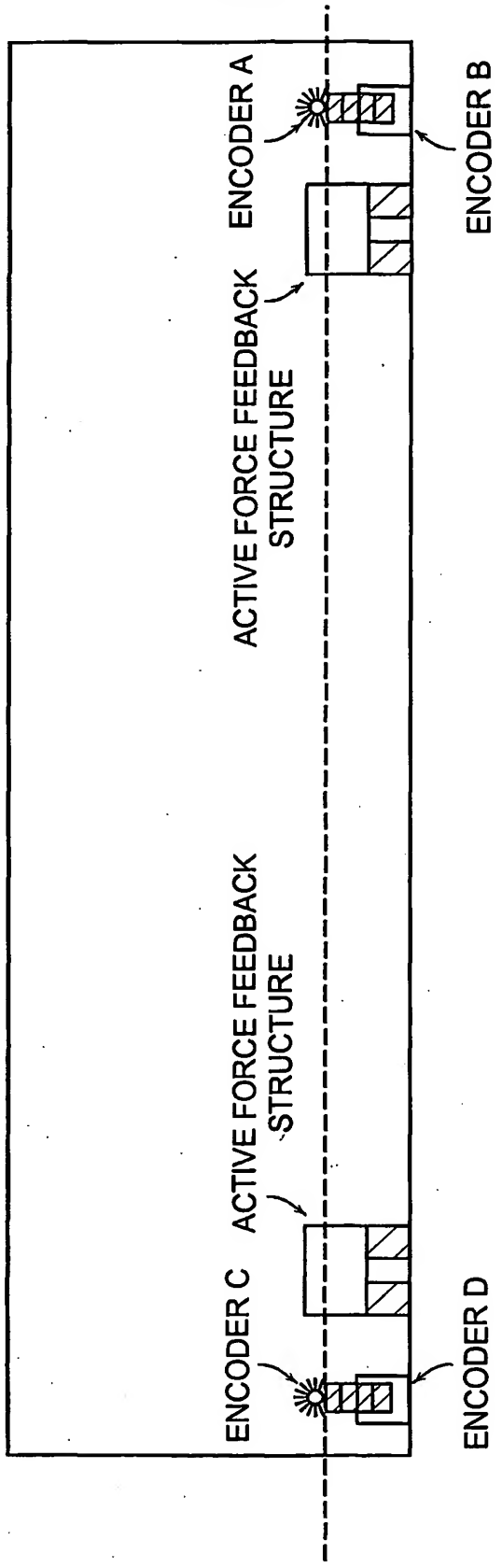

ENCODER A
ENCODER B
ACTIVE FORCE FEEDBACK STRUCTURE
ACTIVE FORCE FEEDBACK STRUCTURE
ENCODER C
ENCODER D

FIG. 5A

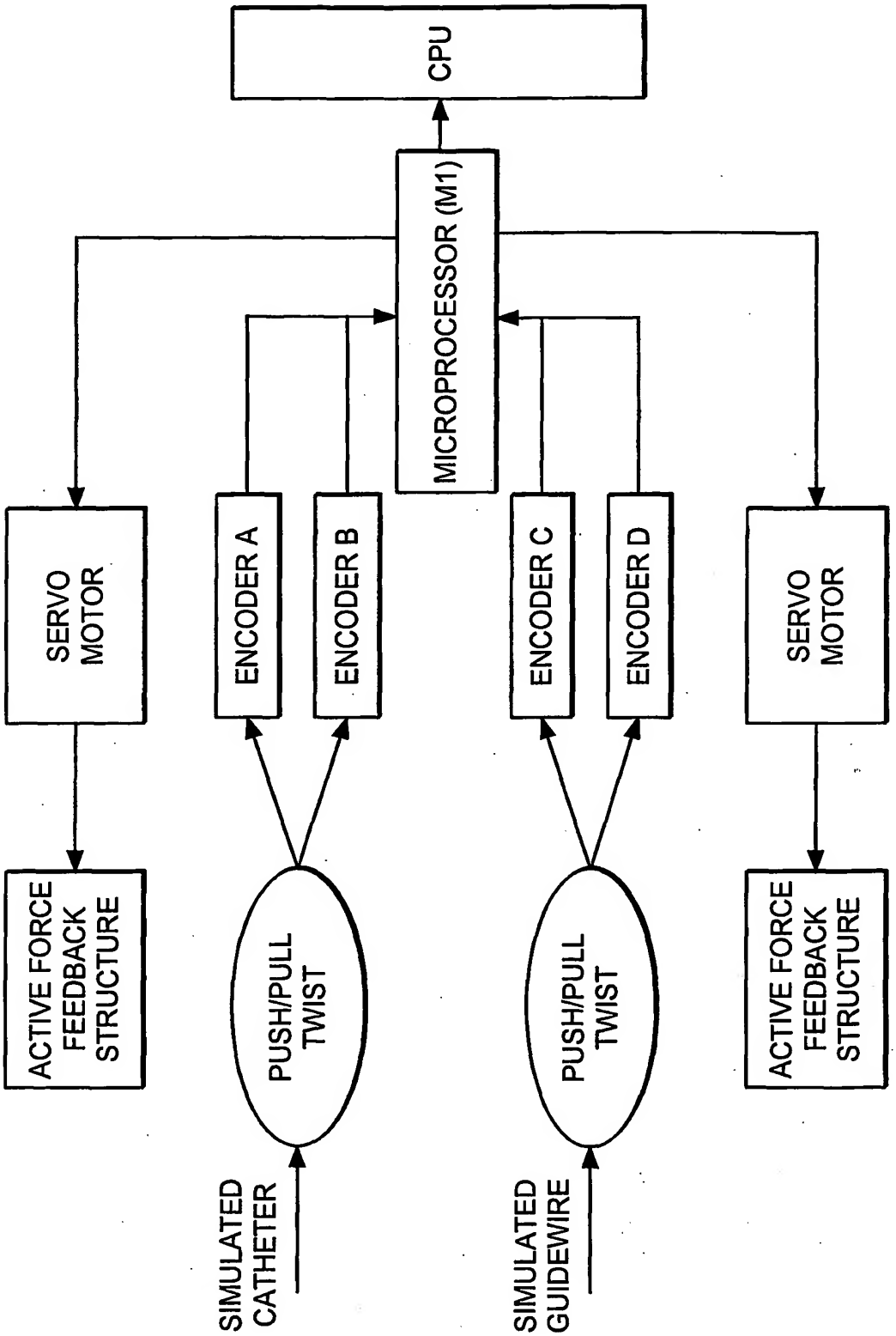

CPU
MICROPROCESSOR (M1)
SERVO MOTOR
ENCODER A
ENCODER B
ENCODER C
ENCODER D
SERVO MOTOR
ACTIVE FORCE FEEDBACK STRUCTURE
PUSH/PULL TWIST
PUSH/PULL TWIST
ACTIVE FORCE FEEDBACK STRUCTURE
SIMULATED CATHETER
SIMULATED GUIDEWIRE

FIG. 5B

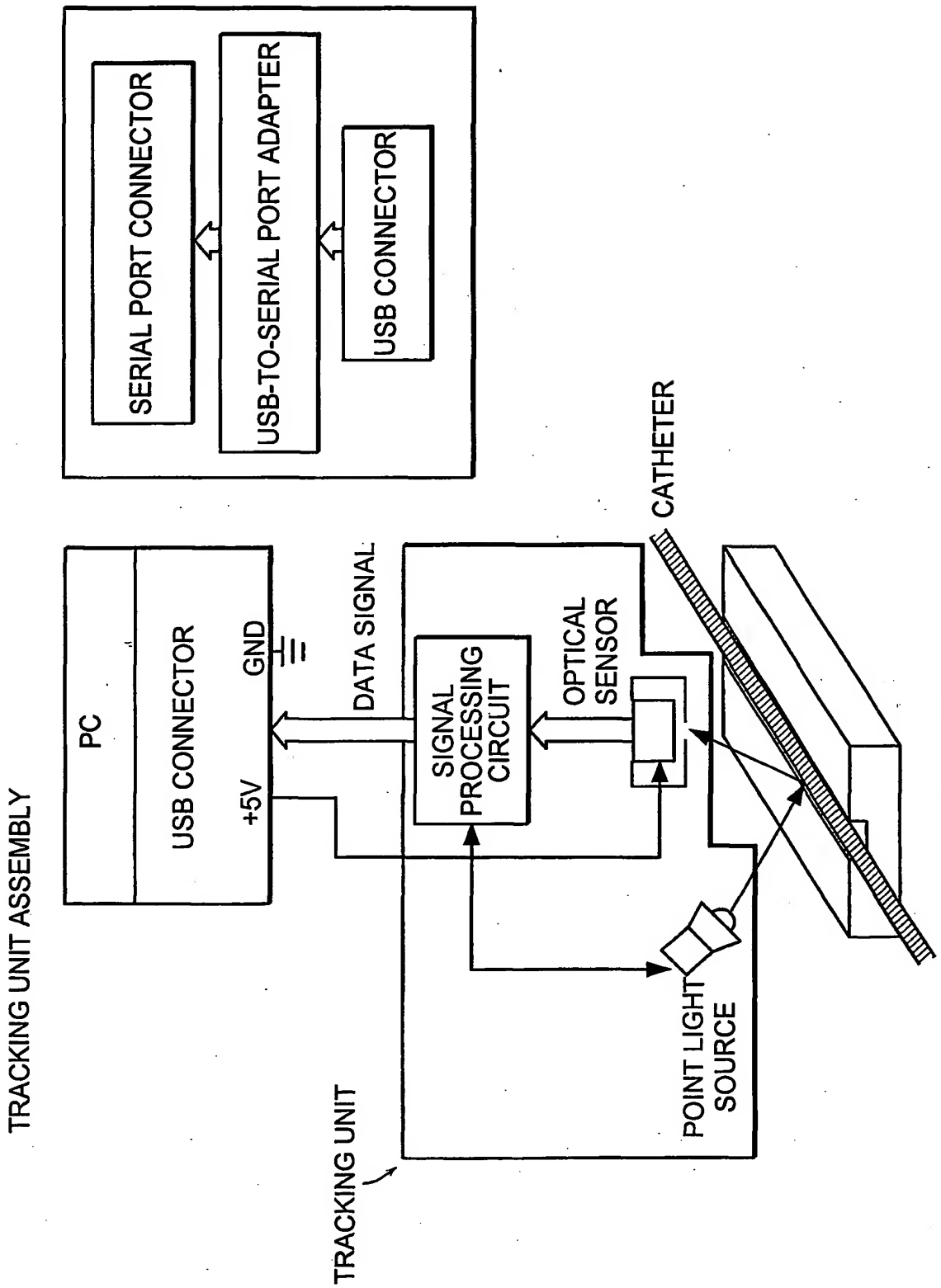

SERIAL PORT CONNECTOR
USB-TO-SERIAL PORT ADAPTER
USB CONNECTOR
CATHETER
TRACKING UNIT ASSEMBLY
PC
USB CONNECTOR
GND
+5V
DATA SIGNAL
SIGNAL PROCESSING CIRCUIT
OPTICAL SENSOR
TRACKING UNIT
POINT LIGHT SOURCE

FIG. 6A

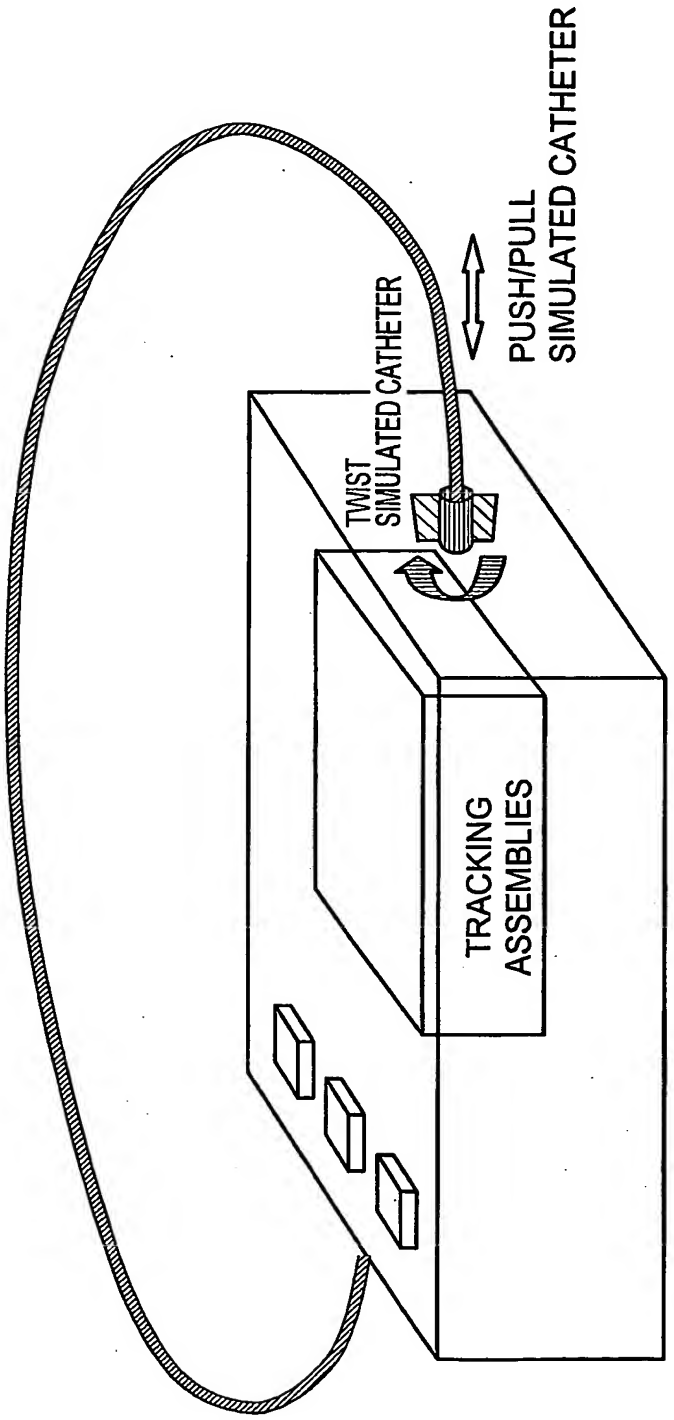

PUSH/PULL
SIMULATED CATHETER
TWIST
SIMULATED CATHETER
TRACKING
ASSEMBLIES

FIG. 6B

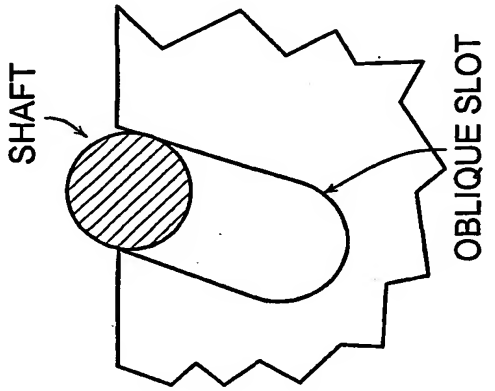

SHAFT
OBLIQUE SLOT

FIG. 7B

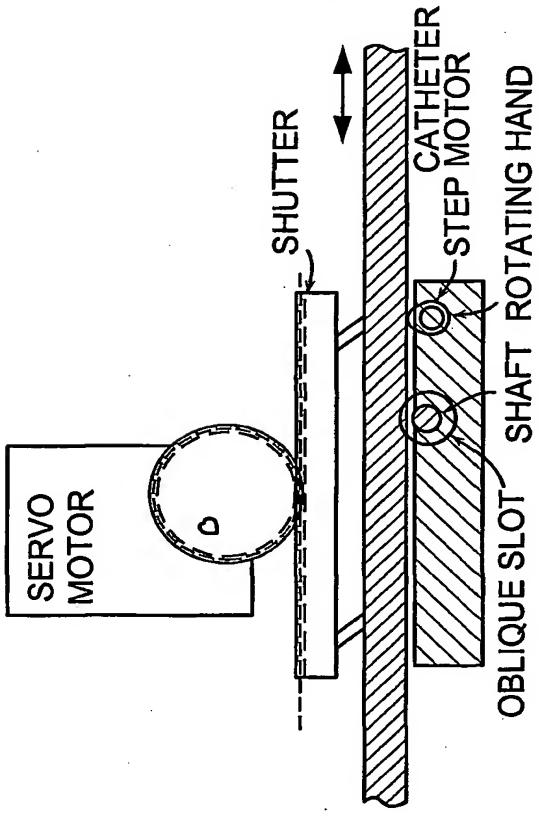

SERVO MOTOR
SHUTTER
CATHETER
STEP MOTOR
ROTATING HAND
SHAFT
OBLIQUE SLOT

FIG. 7A

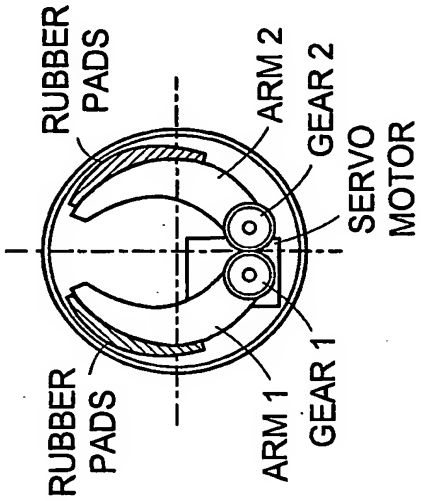

RUBBER PADS
ARM 2
GEAR 2
SERVO MOTOR
RUBBER PADS
ARM 1
GEAR 1

FIG. 8B

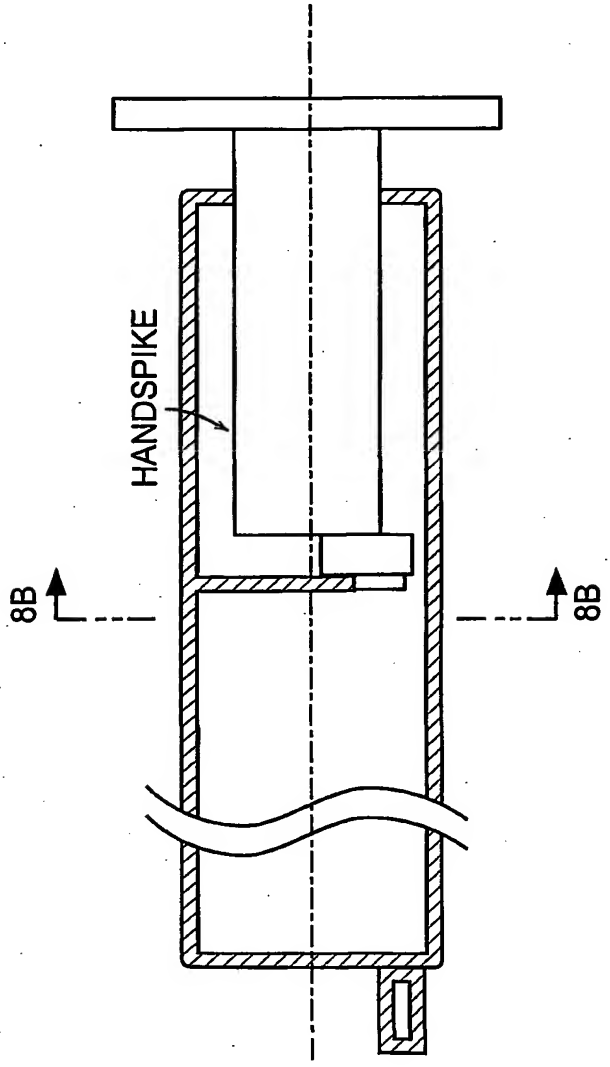

HANDSPIKE
8B
8B

FIG. 8A

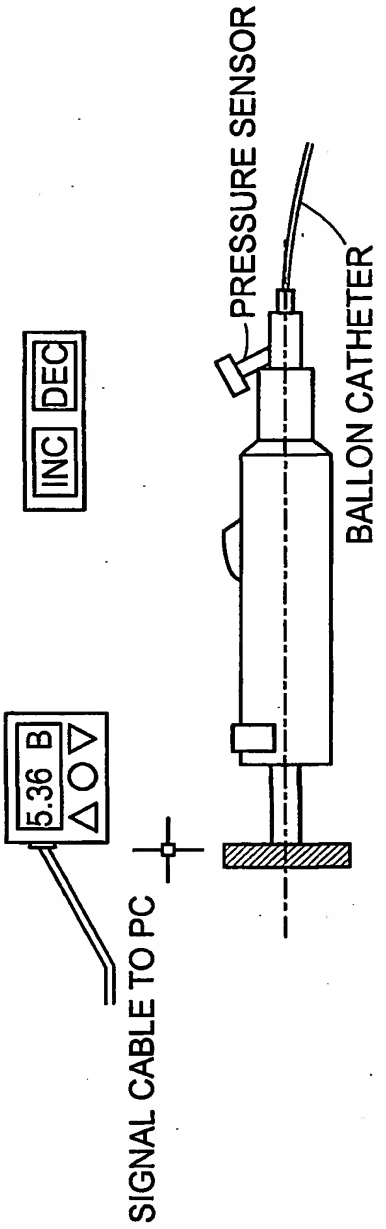

PRESSURE SENSOR
BALLON CATHETER
DEC
INC
5.36 B
SIGNAL CABLE TO PC

FIG. 9

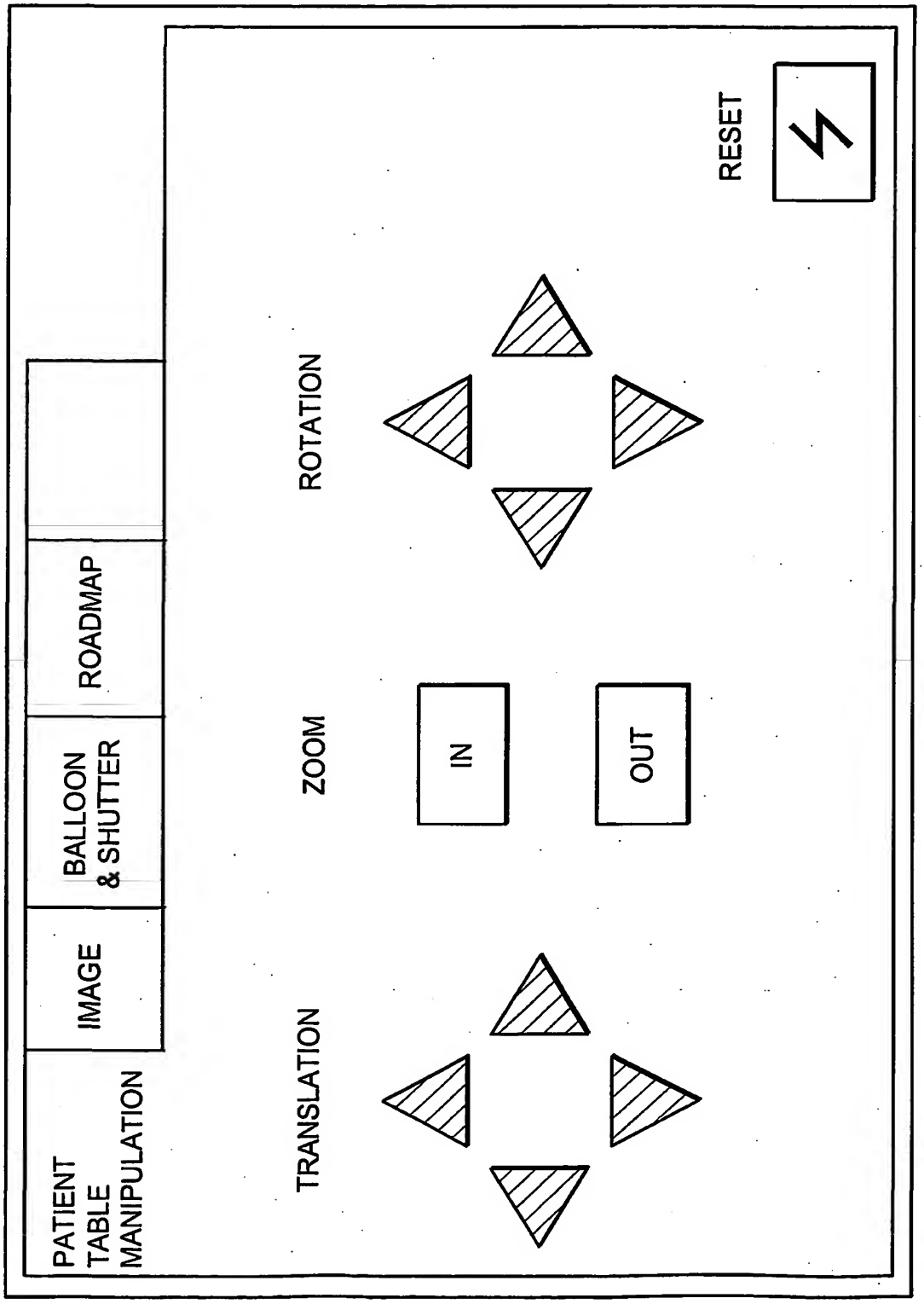

PATIENT TABLE MANIPULATION
IMAGE
BALLOON & SHUTTER
ROADMAP
TRANSLATION
ZOOM
IN
OUT
ROTATION
RESET

FIG. 10A

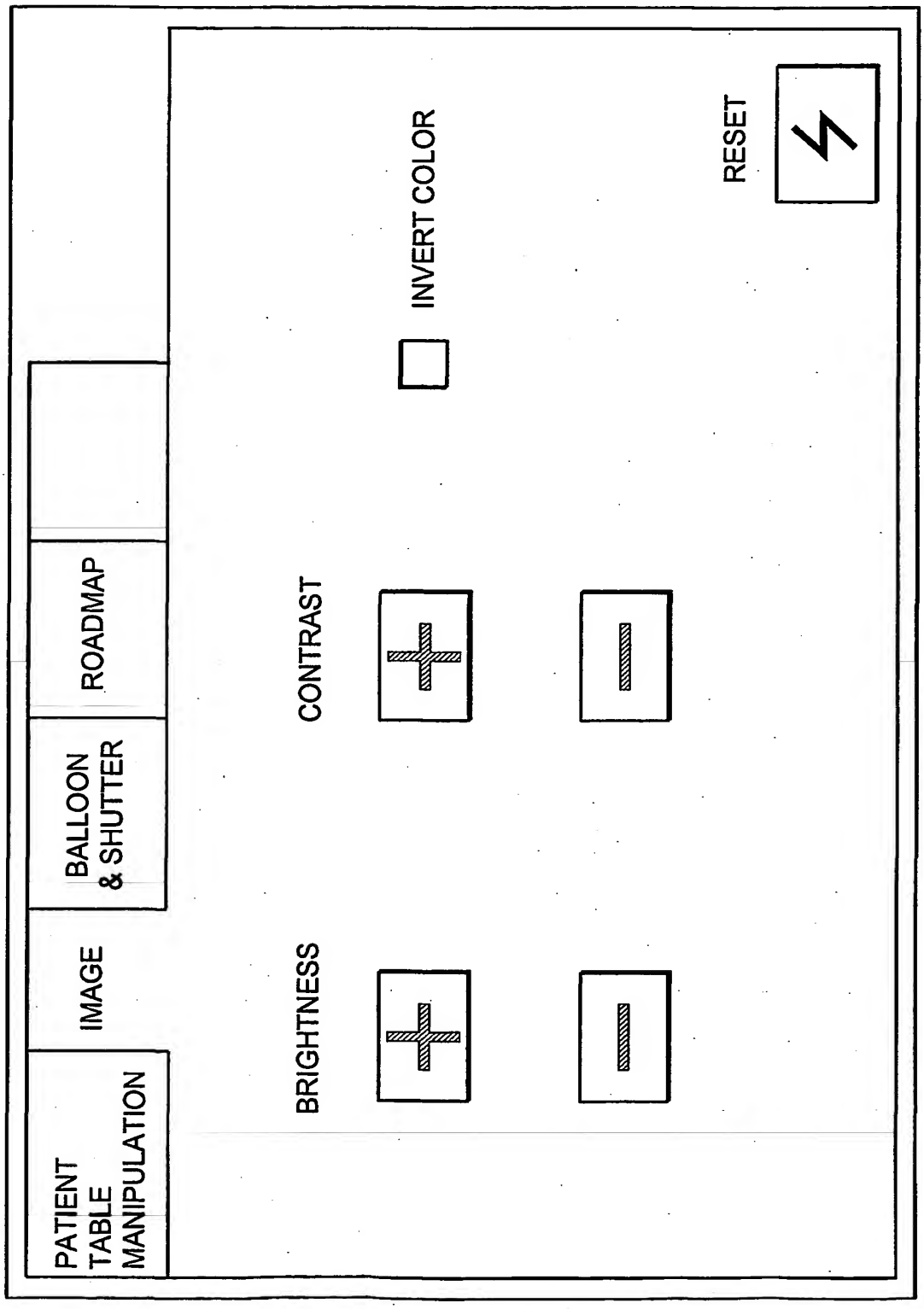

PATIENT TABLE MANIPULATION
IMAGE
BALLOON & SHUTTER
ROADMAP
BRIGHTNESS
CONTRAST
INVERT COLOR
RESET

FIG 10R

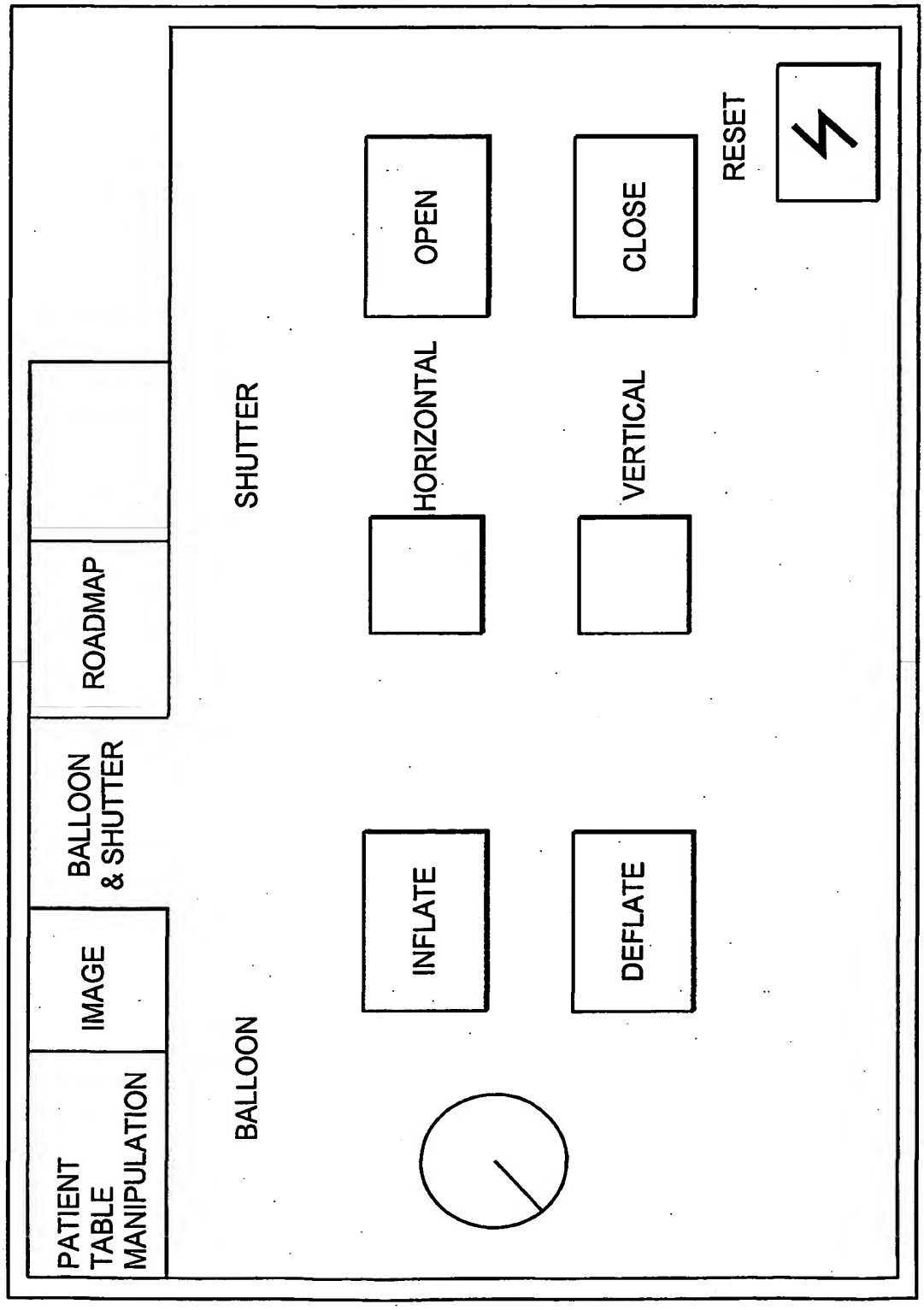

PATIENT TABLE MANIPULATION
IMAGE
BALLOON & SHUTTER
ROADMAP
BALLOON
SHUTTER
INFLATE
DEFLATE
HORIZONTAL
VERTICAL
OPEN
CLOSE
RESET

FIG. 10C

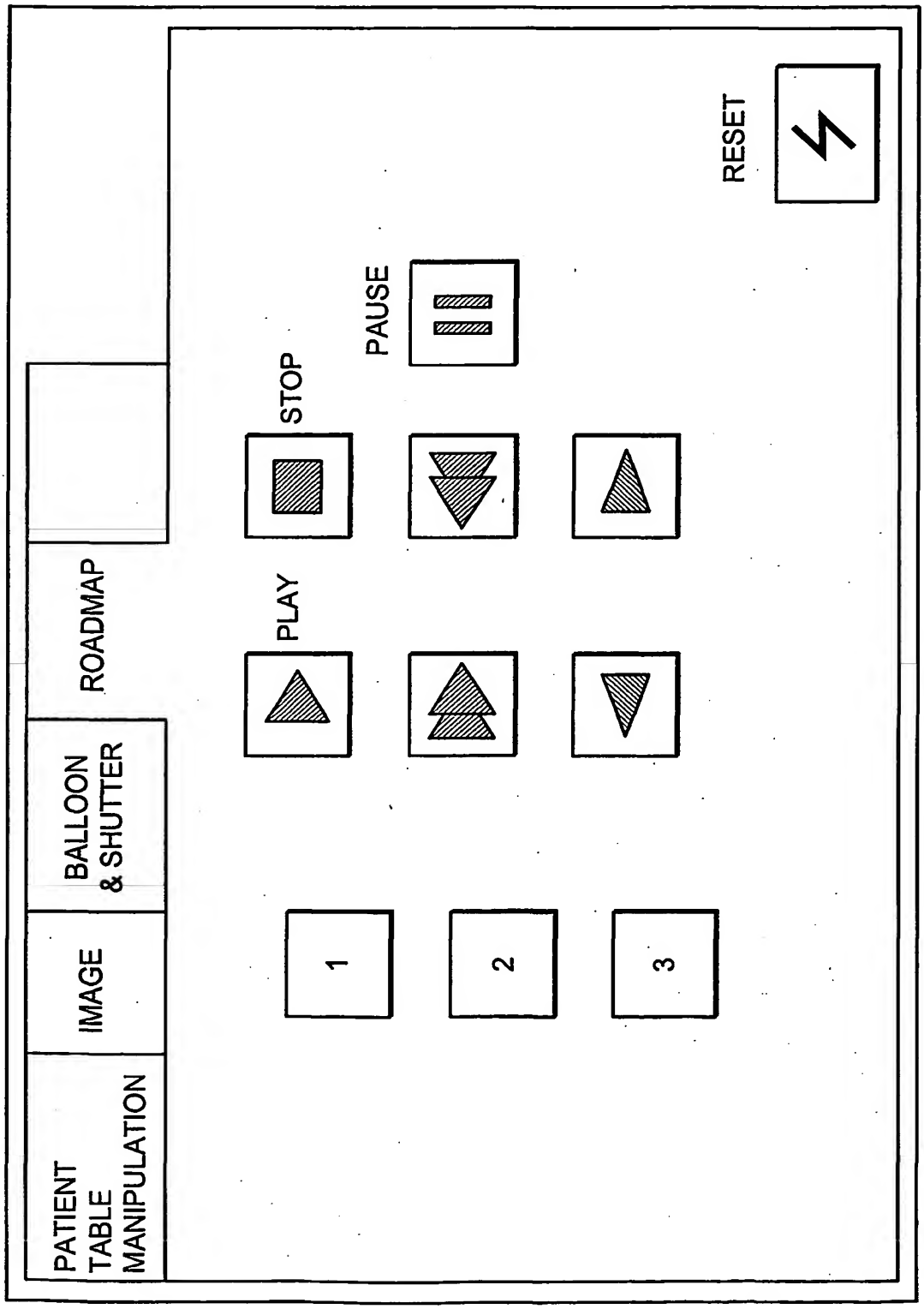

PATIENT TABLE MANIPULATION
IMAGE
BALLOON & SHUTTER
ROADMAP
PLAY
STOP
PAUSE
RESET
1
2
3

FIG. 10D

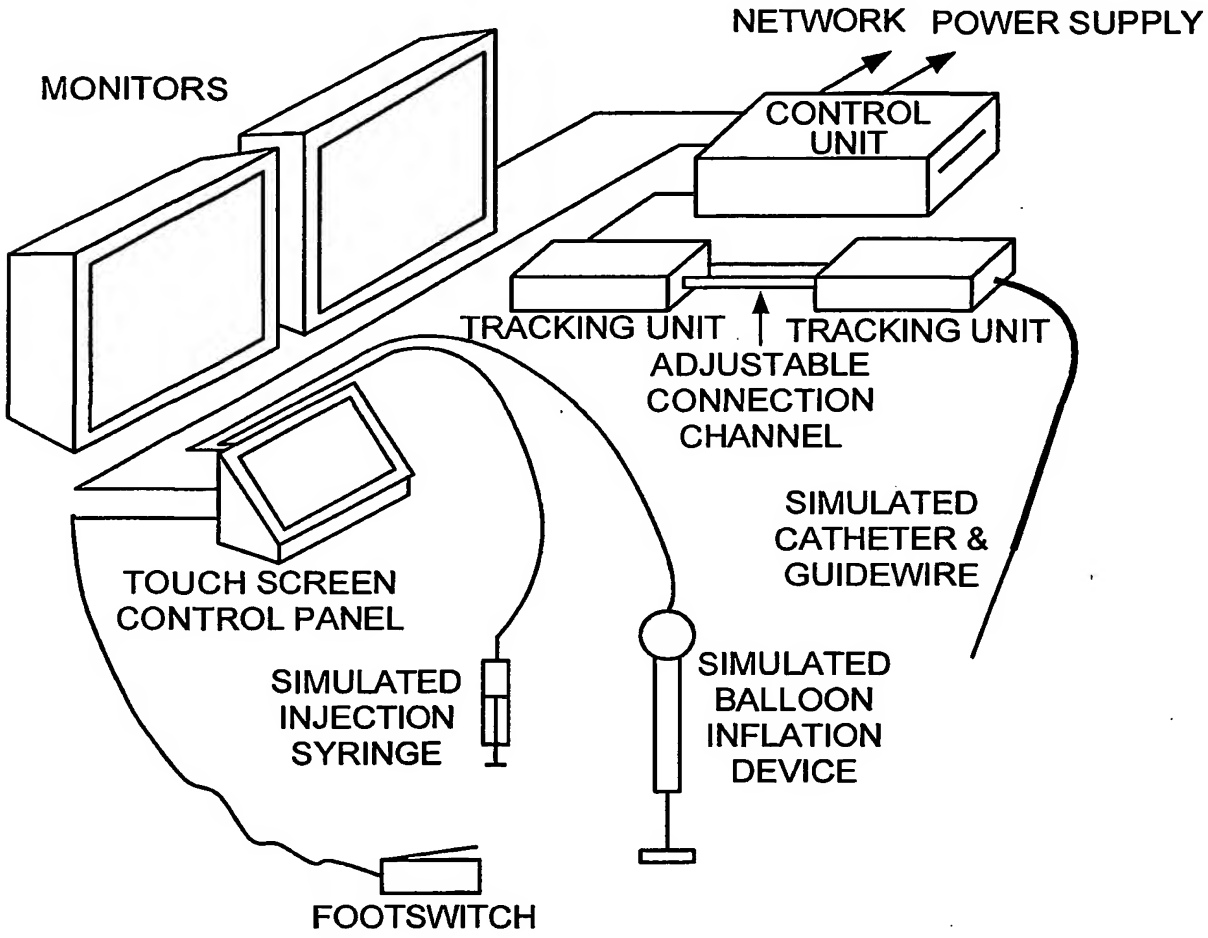

NETWORK
POWER SUPPLY
MONITORS
CONTROL UNIT
TRACKING UNIT
TRACKING UNIT
ADJUSTABLE CONNECTION CHANNEL
SIMULATED CATHETER & GUIDEWIRE
TOUCH SCREEN CONTROL PANEL
SIMULATED INJECTION SYRINGE
SIMULATED BALLOON INFLATION DEVICE
FOOTSWITCH

FIG. 11

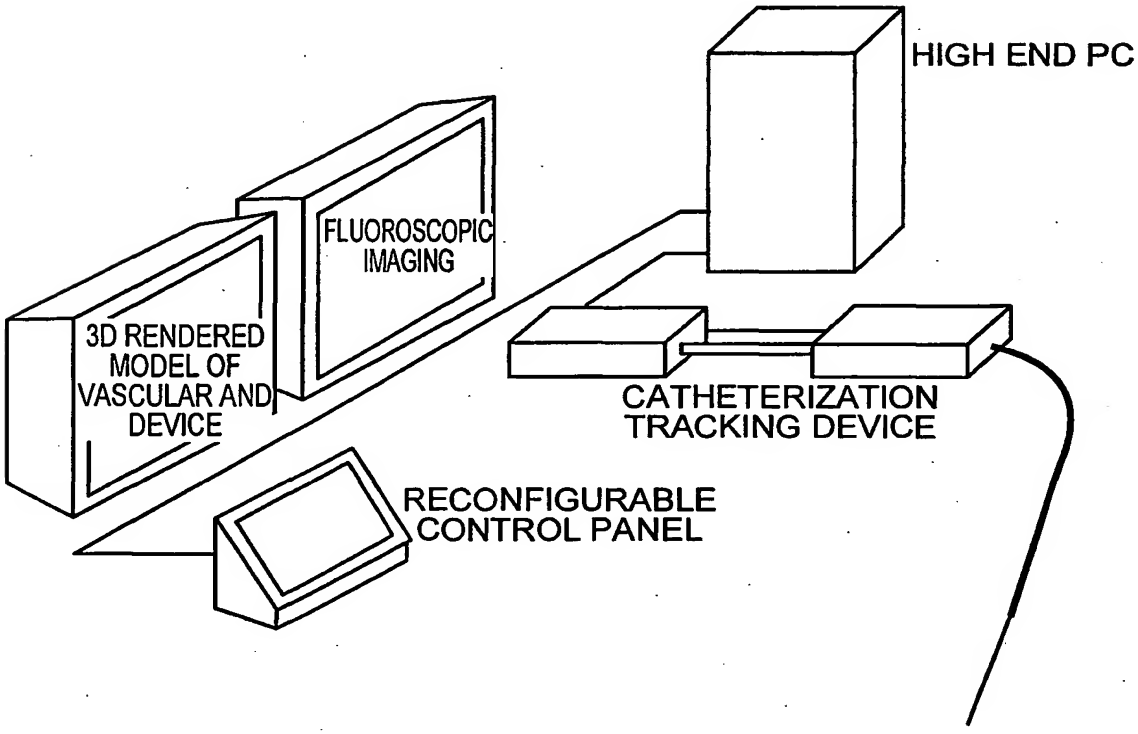

HIGH END PC
FLUOROSCOPIC IMAGING
3D RENDERED MODEL OF VASCULAR AND DEVICE
CATHETERIZATION TRACKING DEVICE
RECONFIGURABLE CONTROL PANEL

FIG. 12

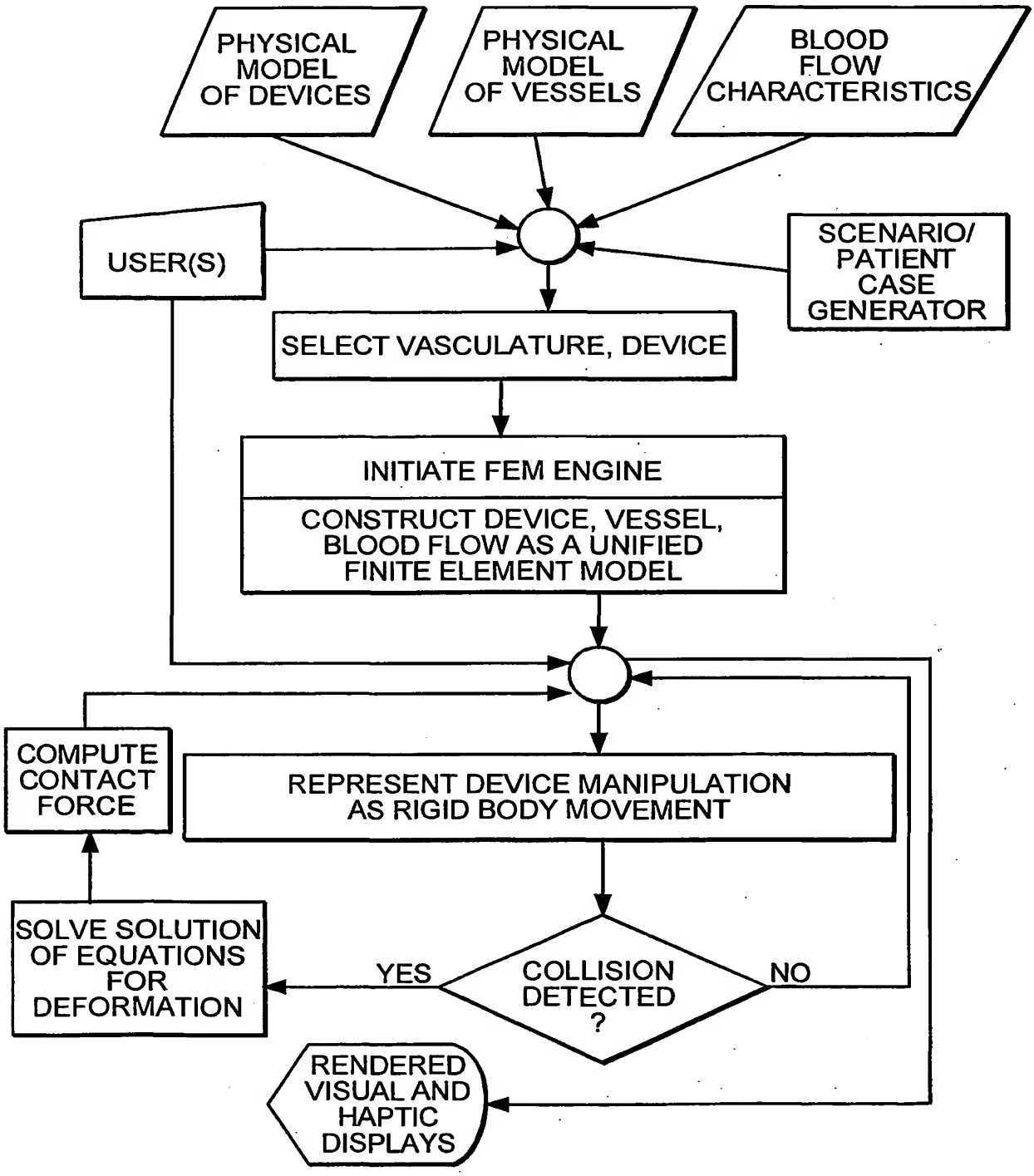

PHYSICAL MODEL OF DEVICES
PHYSICAL MODEL OF VESSELS
BLOOD FLOW CHARACTERISTICS
USER(S)
SCENARIO/ PATIENT CASE GENERATOR
SELECT VASCULATURE, DEVICE
INITIATE FEM ENGINE
CONSTRUCT DEVICE, VESSEL, BLOOD FLOW AS A UNIFIED FINITE ELEMENT MODEL
COMPUTE CONTACT FORCE
REPRESENT DEVICE MANIPULATION AS RIGID BODY MOVEMENT
SOLVE SOLUTION OF EQUATIONS FOR DEFORMATION
YES
COLLISION DETECTED ?
NO
RENDERED VISUAL AND HAPTIC DISPLAYS

FIG. 13

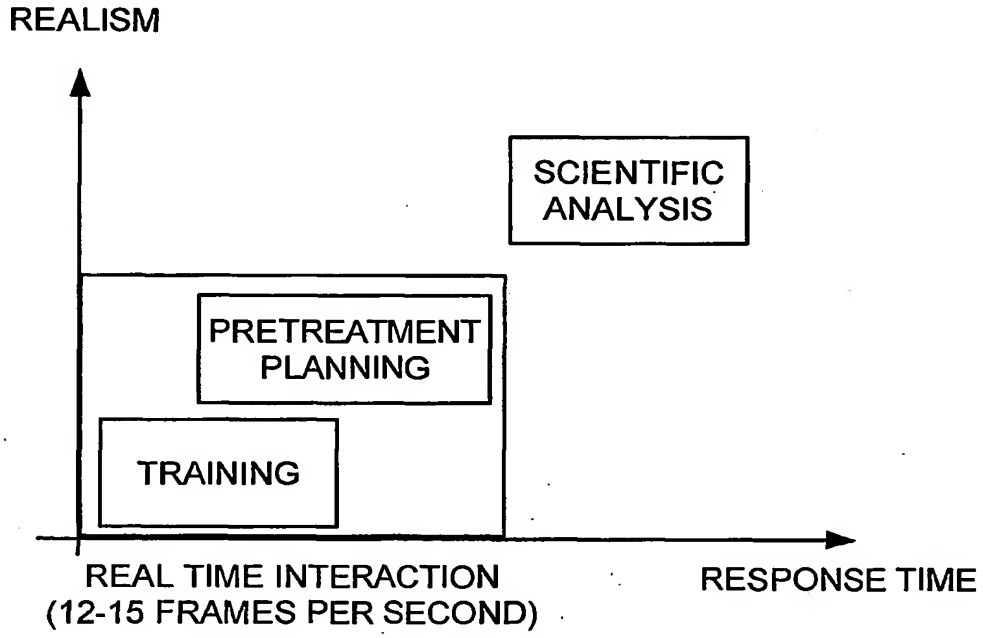

REALISM
SCIENTIFIC ANALYSIS
PRETREATMENT PLANNING
TRAINING
REAL TIME INTERACTION (12-15 FRAMES PER SECOND)
RESPONSE TIME

FIG. 14

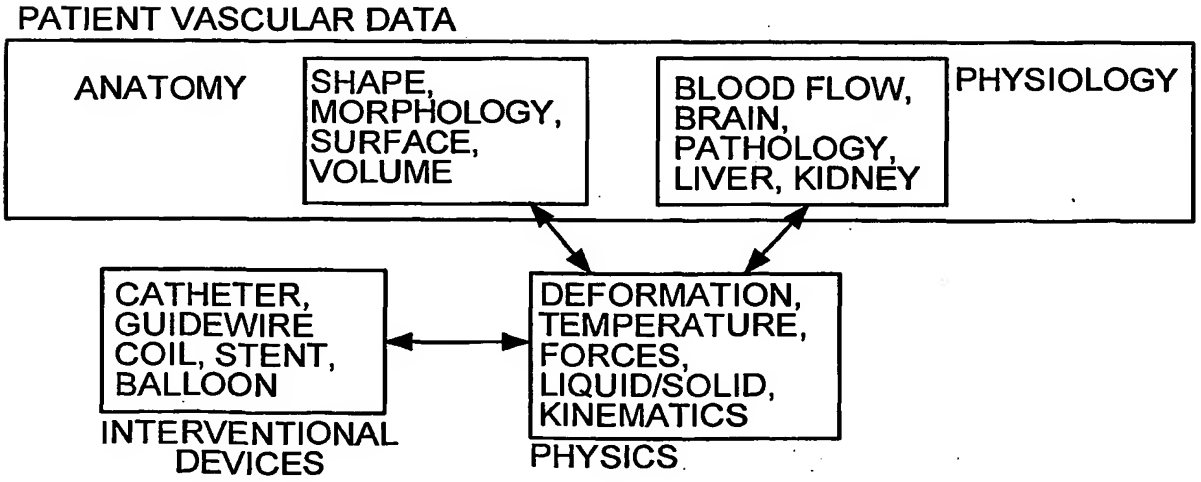

PATIENT VASCULAR DATA
ANATOMY
SHAPE, MORPHOLOGY, SURFACE, VOLUME
BLOOD FLOW, BRAIN, PATHOLOGY, LIVER, KIDNEY
PHYSIOLOGY
CATHETER, GUIDEWIRE COIL, STENT, BALLOON
INTERVENTIONAL DEVICES
DEFORMATION, TEMPERATURE, FORCES, LIQUID/SOLID, KINEMATICS
PHYSICS

FIG. 15

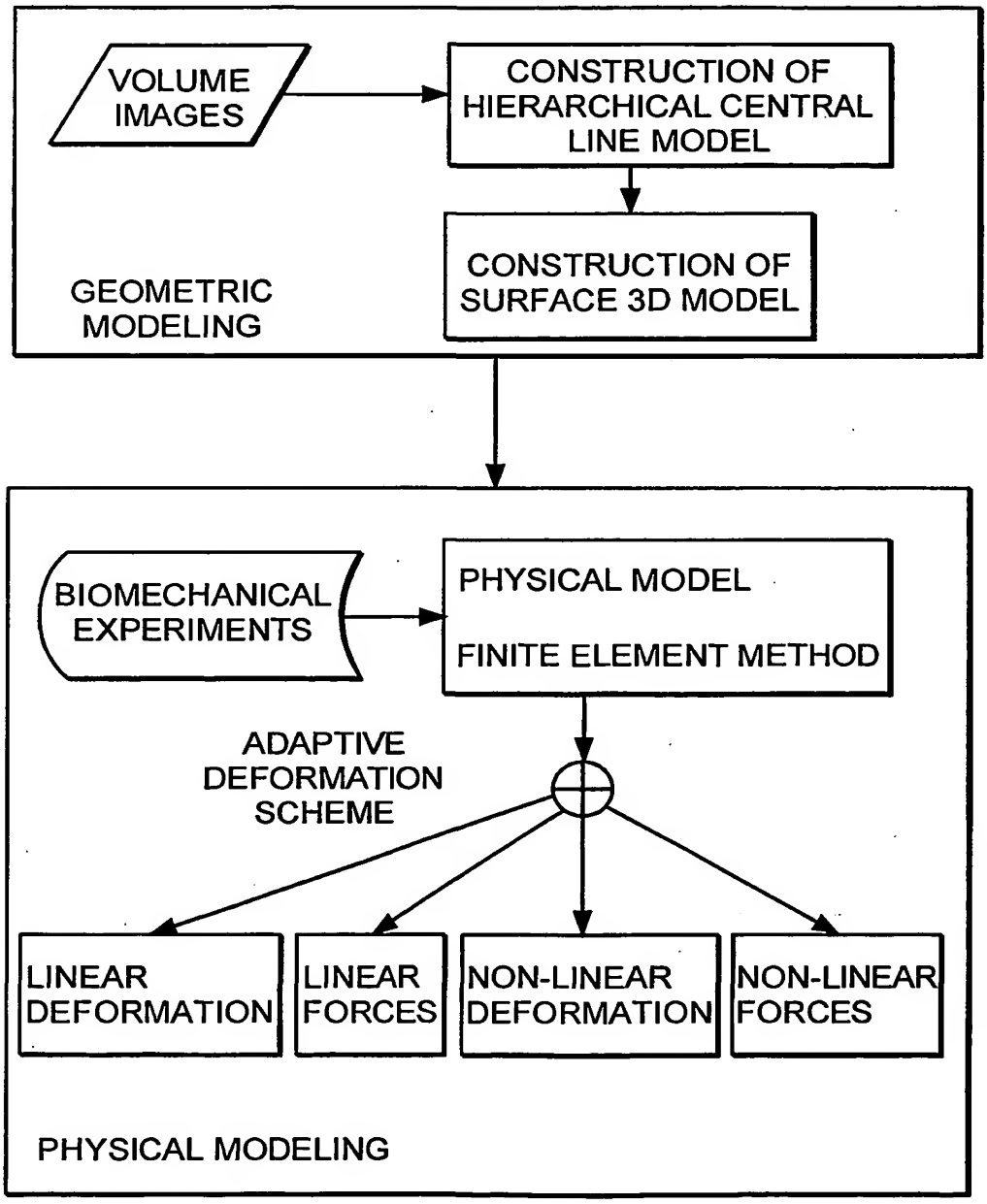

VOLUME IMAGES
CONSTRUCTION OF HIERARCHICAL CENTRAL LINE MODEL
CONSTRUCTION OF SURFACE 3D MODEL
GEOMETRIC MODELING
BIOMECHANICAL EXPERIMENTS
PHYSICAL MODEL
FINITE ELEMENT METHOD
ADAPTIVE DEFORMATION SCHEME
LINEAR DEFORMATION
LINEAR FORCES
NON-LINEAR DEFORMATION
NON-LINEAR FORCES
PHYSICAL MODELING

FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/06604

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : F41G 3/26
US CL : 434/262
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : Please See Continuation Sheet

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,106,301 A (MERRIL) 22 August 2000 (22.08.2000), See the entire document.	1-31, 33-73
Y	US 4,642,055 A (SALITERMAN) 10 February 1987 (10.02.1987), See figures 1-18, column 3, line 28 to column 7, line 27.	1-31, 33-37, 53, 54, 55,
Y	US 5,800,179 A (BAILEY) 01 Septermber 1998 (01.09.1998), See figure 1, 6; column 3, line 45 to column 4, line 28, column 7, lines 27-41.	19-22,
Y	US 4,907,973 A (HON) 13 March 1990 (13.03.1990), See the entire document.	19-22, 53
Y	US 6,104,780 A (HANOVER et al) 15 August 2000 (15.08.2000), See column 1, line 13 to column 4, line 11.	23
A	US 5,800,177 (GILLIO) 01 September 1998 (01.09.1998), See the entire document.	
A	US 5,289,373 A (ZARGE et al) 22 February 1994 (22.02.1994), See the entire document.	
A	GB 2,288,686 A (BRETT et al) 25 October 1995 (25.10.1995), See the entire document	
A	WO 99/42978 (PLAYTER et al) 26 August 1999 (26.08.99), See the entire document.	

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
10 June 2002 (10.06.2002)

Date of mailing of the international search report
03 JUL 2002

Name and mailing address of the ISA/US
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Washington, D.C. 20231
Facsimile No. (703)305-3230

Authorized officer
Mark Sager
Telephone No. 703 308 0785

Shelia Veney
Paralegal Specialist
Group 3700

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/06604

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,771,181 (MOORE et al) 23 June 1998 (24.06.1998), See the entire document.	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/06604

Continuation of B. FIELDS SEARCHED Item 1:
434/262,268,272
703/7